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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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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Technical Expert Panel (TEP)

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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EXECUTIVE SUMMARY

INTRODUCTION

The Veterans Health Administration (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. 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). 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 in systematic reviews, in the form of evidence maps. The evidence maps will be used to guide and support decision-making about these treatment modalities in the VHA. 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?

METHODS

Data Sources and Searches

We developed search strategies in consultation with a research librarian. We searched multiple data sources from database inception through March 2018 for systematic reviews and meta-analyses of guided imagery, biofeedback, or hypnosis.

Study Selection

Using pre-specified inclusion criteria, 2 investigators independently assessed all abstracts and full-text articles for inclusion. We included systematic reviews that focused explicitly on the interventions of interest, included controlled trials in subjects defined by specific medical conditions or risk groups, and met pre-specified quality criteria. 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.

Data Abstraction and Quality Assessment

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 separate data according to 4 outcome categories: diagnosis-related outcomes, secondary outcomes, global health outcomes, and harms.

Data Synthesis and Analysis

Using the vector graphics in Microsoft Excel (2016), we generated scatter plots representing the findings in 2 dimensions: level of effectiveness 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). We also provide a brief narrative synthesis of the findings.

We classified the estimate of effect into 4 categories:

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; 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 with a positive effect.

4) Positive effect: numerous studies or a large sample showing a positive effect

We classified the levels of confidence in the evidence as follows:

a) High: Consistent findings from larger studies with low risk of bias (ROB).

b) Moderate: Larger studies that may have limitations in study quality, applicability, or consistency of findings.

c) Low: Small sample size or major deficiencies in the body of evidence.

d) 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.

RESULTS

Results of Literature Search

Our search of electronic databases, bibliographies, and other sources resulted in a total of 2,533 citations. After dual review of titles, abstracts, and full-text articles, we selected 40 systematic reviews representing the most recent and comprehensive evidence available on each intervention, as applied to distinct medical conditions and target populations.

Summary of Results for 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?

We identified 12 systematic reviews examining the effectiveness of guided imagery interventions for anxiety, arthritis, cancer, cardiac surgery, intensive care unit (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 populations studied, but the findings were mixed and the levels of confidence in the evidence were low overall.

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

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 evidence that biofeedback can reduce pain resulting from migraines and tension-type headaches, and that as an adjunct to pelvic floor muscle training (PFMT) it can provide benefit to men experiencing urinary incontinence after a prostatectomy. 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, nor is biofeedback effective for secondary or global outcomes in fibromyalgia or a viable alternative to pharmacologic intervention for hypertension. Findings for most conditions were insufficient to form a conclusion.

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

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, for reducing anxiety associated with patients with cancer, and for symptoms experienced during breast cancer treatment. We identified low-confidence evidence that hypnosis provides no benefit for smoking cessation or schizophrenia, nor is hypnosis effective for secondary or global outcomes in patients with labor and childbirth or irritable bowel syndrome (IBS).

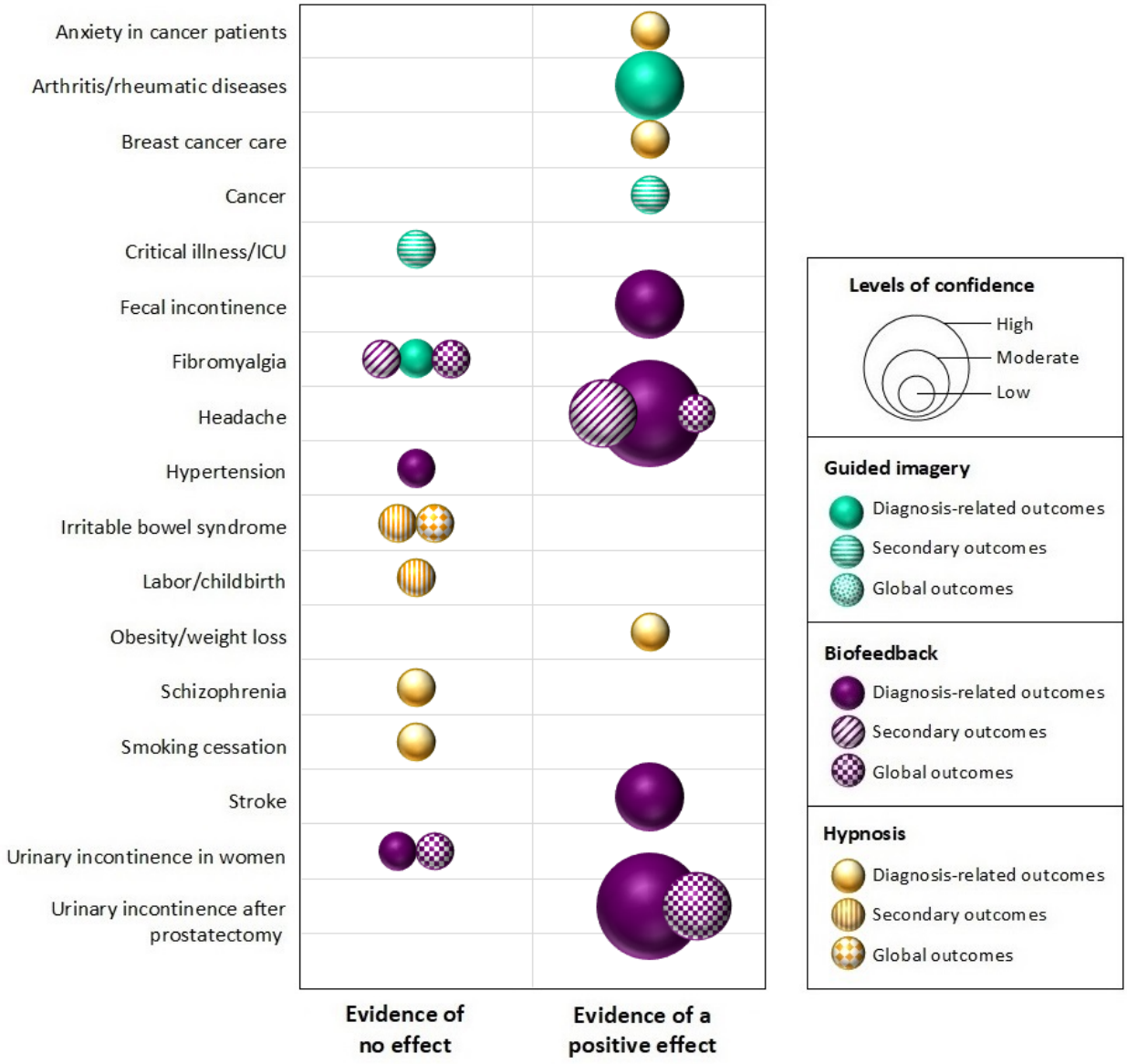
DISCUSSION

Key Findings

The evidence maps provide a broad overview of the evidence base regarding guided imagery, biofeedback, and hypnosis interventions. The figure on the following page shows the health conditions for which interventions had either a consistently positive effect for any outcome, or consistent evidence of no effect.

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 effective for urinary incontinence after prostatectomy, fecal incontinence, balance and gait in stroke patients, and headache.

Executive Summary Figure 1. 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



Limitations

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 approaches, given the previously listed constraints. These maps instead provide broad "brushstrokes" regarding the potential benefits of these interventions. 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.

Similarly, evidence maps provide a broad overview about evidence gaps, but cannot be definitive in determining an absence of evidence. Data for these evidence maps came from systematic reviews: therefore, individual trials not included in prior reviews or areas in which there were no reviews meeting inclusion criteria are not represented in these evidence maps. It is possible that the maps have identified areas of insufficient evidence in which there is individual trial data, or systematic reviews that did not meet our minimum quality criteria.

Research Gaps/Future Research

The level of confidence for the vast majority of outcomes for most of the health conditions studied 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 often inadequate were a limited number of trials/small combined sample sizes, and methodologic limitations in the included RCTs, such as lack of blinding.

Data regarding harms were poorly reported. From a clinical and biologic plausibility standpoint, however, it is unlikely that these 3 interventions are associated with clinically significant harms.

The interventions and health conditions for which there was evidence of a "potential positive effect" may represent potentially fruitful areas of research. Future studies should be designed to allow for patient blinding, 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 weight loss for obesity, anxiety in patients with cancer, and symptoms during breast cancer treatment, but the levels of confidence in these findings were low.

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 conditions[1] such as anxiety[7] 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:

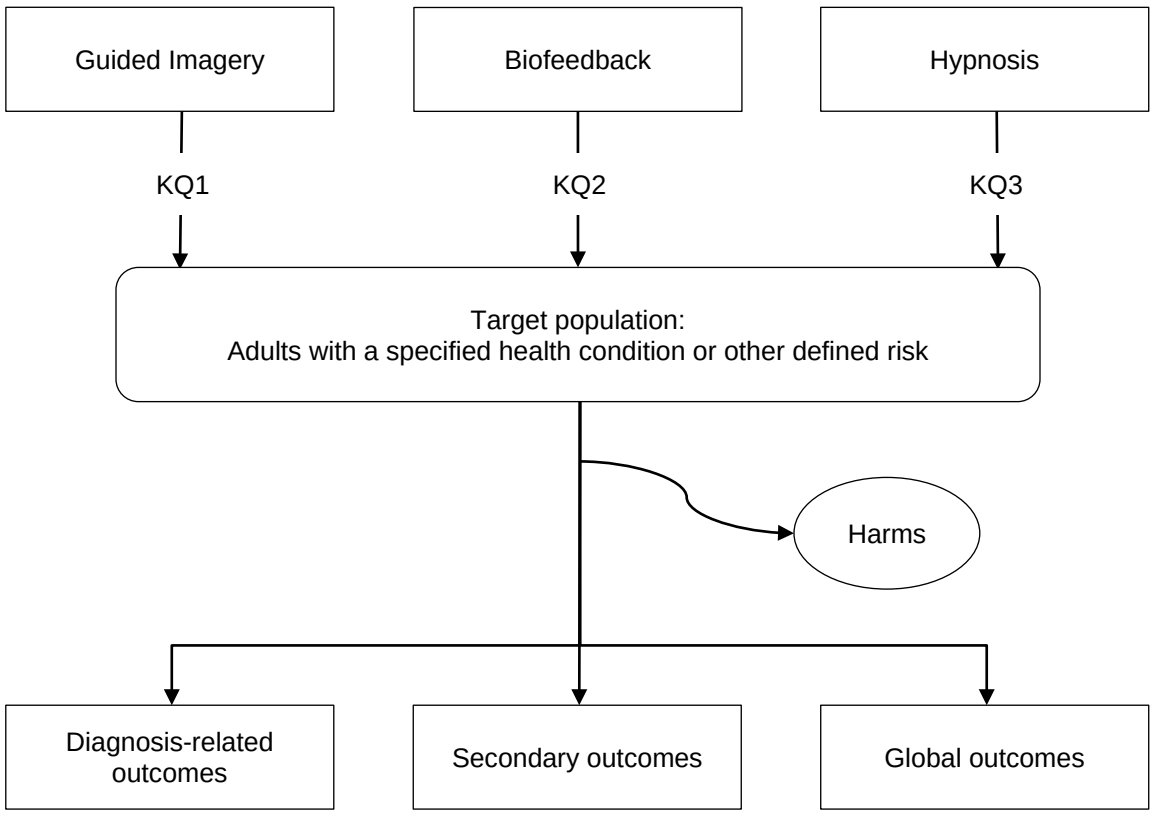
KQ1: In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?

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 stroke[14] and the more broadly defined (including stroke) balance/gait training[15] 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

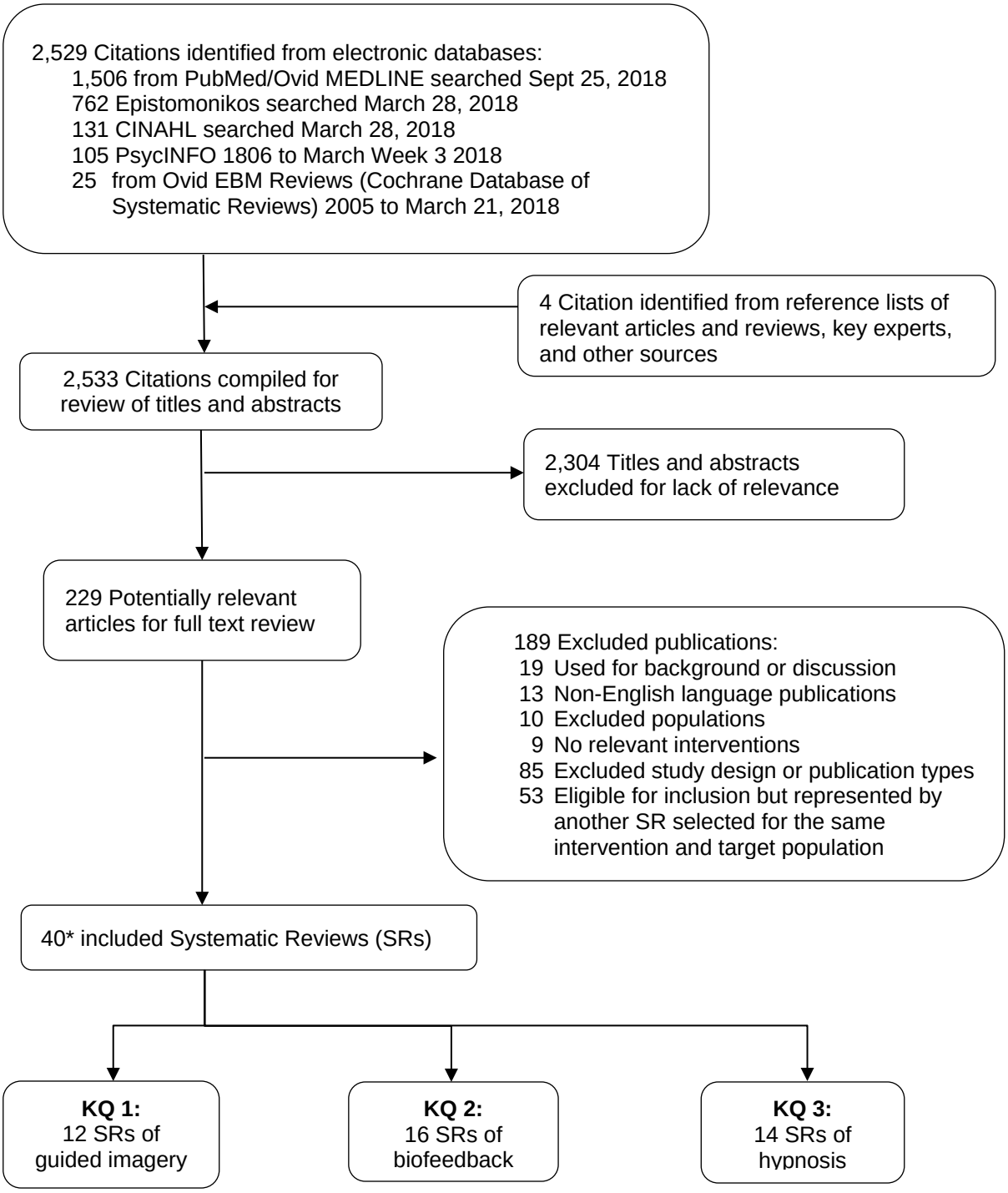
LITERATURE FLOW

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 diseases[20] 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.

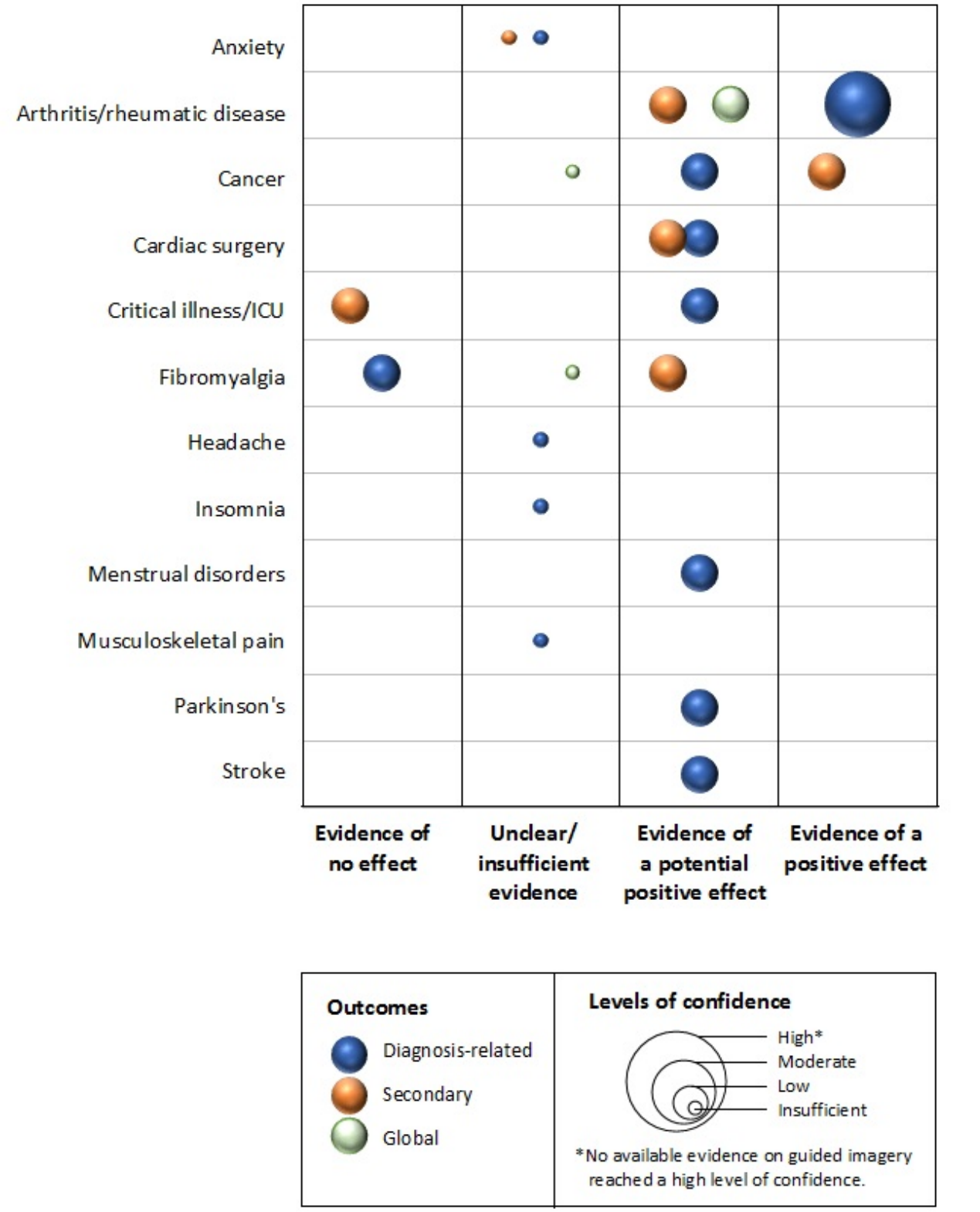
In patients with fibromyalgia,[3] while there was evidence of no effect on pain (4 studies, N=224), there were potential positive effects on secondary outcomes including psychological distress and coping with pain. The level of confidence for both outcomes was low.

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 56[36] to over 3,500[13] (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 heartrate 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 women[51] 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 palsy[21]) 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 hypotension[33]). 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 samples 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

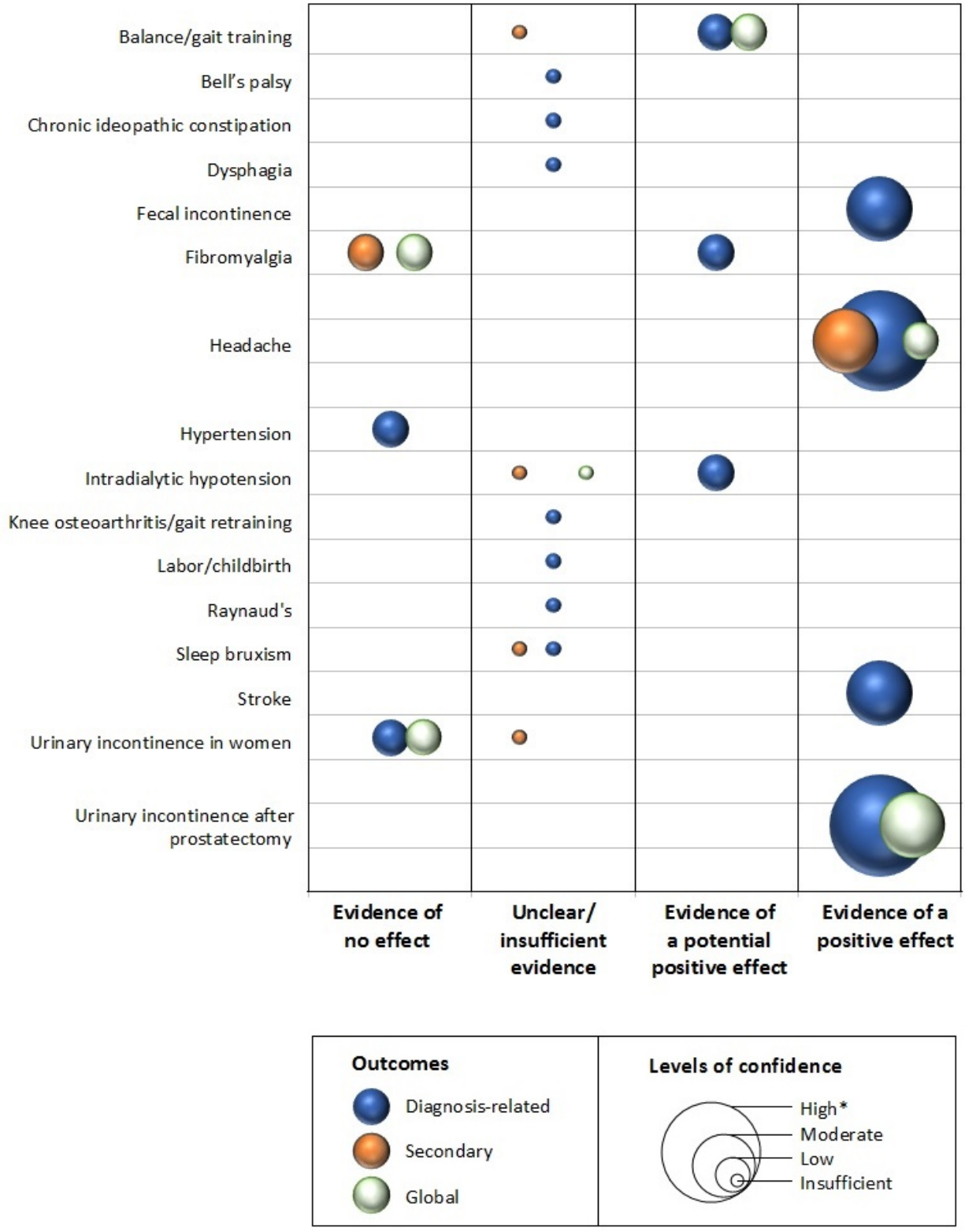
Condition	Biofeedback techniques used	Adjunctive therapies
Balance/Gait training [15]	Wearable plantar pressure sensors (sensor which measures the distribution of plantar pressure, usually when standing or moving) IMU (inertial measurement unit: a type of sensor measuring velocity, acceleration, and 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: Accelerometry: "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" Tongue Manometry: "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" External Laryngeal Manometry: "an air-filled balloon fixed externally to the cervical region to measure changes in pressure during swallowing" Video Endoscopy: "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" Respiratory Inductance Plethysmography: "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
	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 LENS – "a combination of a conventional EEG and sub-threshold photic stimulation in order to change EEG patterns" Sensorimotor Rhythm Training (SMR) – an EEG procedure that aims to facilitate thalamic inhibitory mechanisms"	
Headache[13]	TEMP biofeedback, TEMP + EMG biofeedback, EMG biofeedback, BVP biofeedback, EEG biofeedback, GSR biofeedback 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"	Varied - relaxation
Hypertension [32]	Indirect biofeedback – trains patient to identify and control any stress response that might lead to increased blood pressure Direct biofeedback – direct feedback of blood pressure on a heartbeat from any blood pressure device	Varied - relaxation, meditation, imagery, inner quality management
Intradialytic hypotension [33]	Biofeedback hemodialysis: BVM with dialysate conductivity control, BVM with plasma conductivity-controlled BVM (relative blood volume monitoring). 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)." 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)"	---
Knee osteoarthritis/Gait retraining [36]	Visual, haptic (not specified) – feedback is delivered via visual system or haptic (touch)	---
Labor pain [37]	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) 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	Varied - relaxation, PMR, Lamaze
Raynaud's [46]	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. Thermal feedback + EMG (biofeedback focused on measurement of skin temperature and muscle tension)	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. Weight distribution from a force platform or sensor – 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. Muscle activity from EMG – as previously defined Linear gait parameters from foot sensors – "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." Joint angle from a goniometer – 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 cessation[48] 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 63[28] 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).

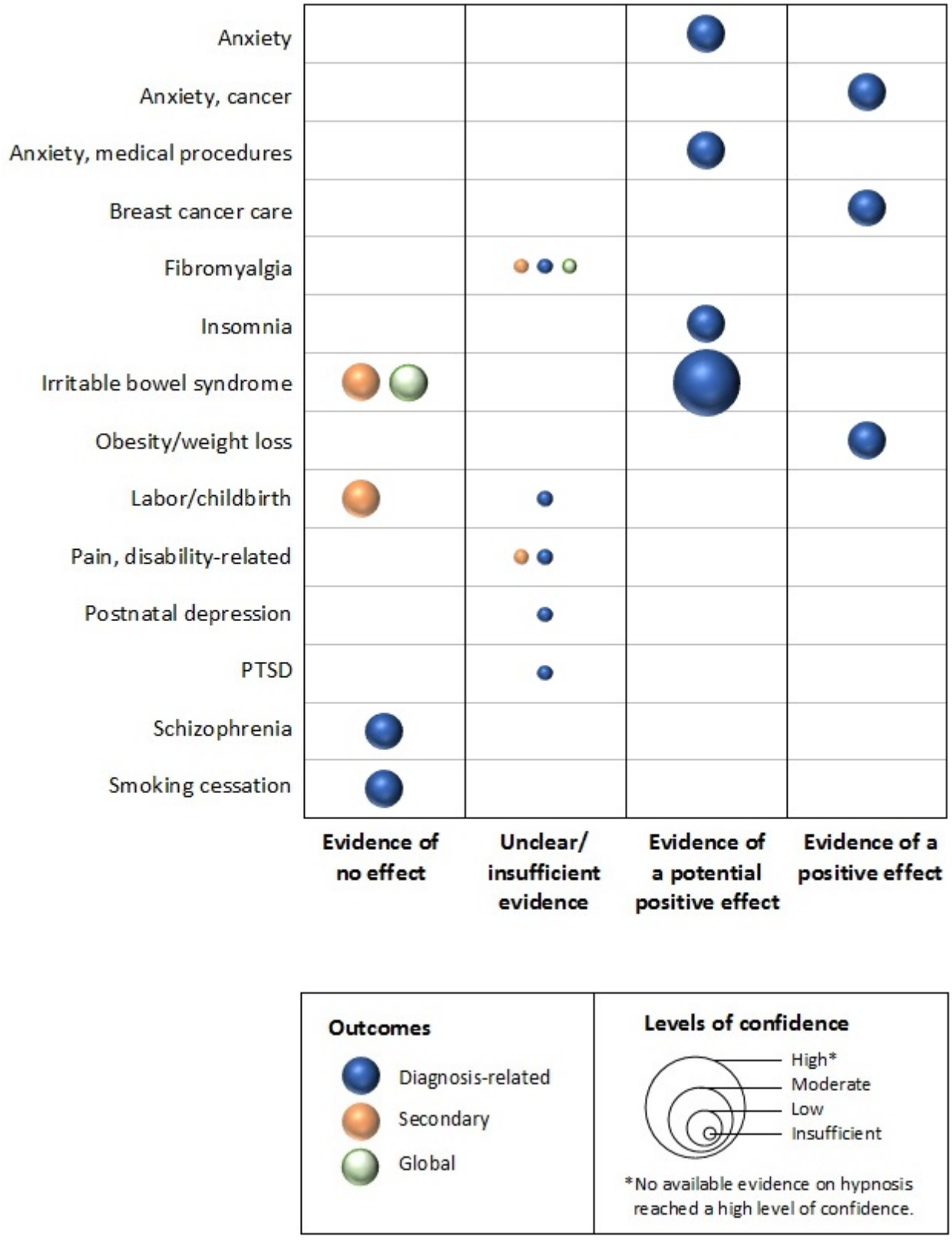
Across conditions, the evidence examining the effectiveness of hypnosis for the treatment of primary/diagnosis-related outcomes depended largely on the condition examined (Figure 5). Although our confidence estimates were low due to methodological concerns about the trials included in the SRs, there 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.

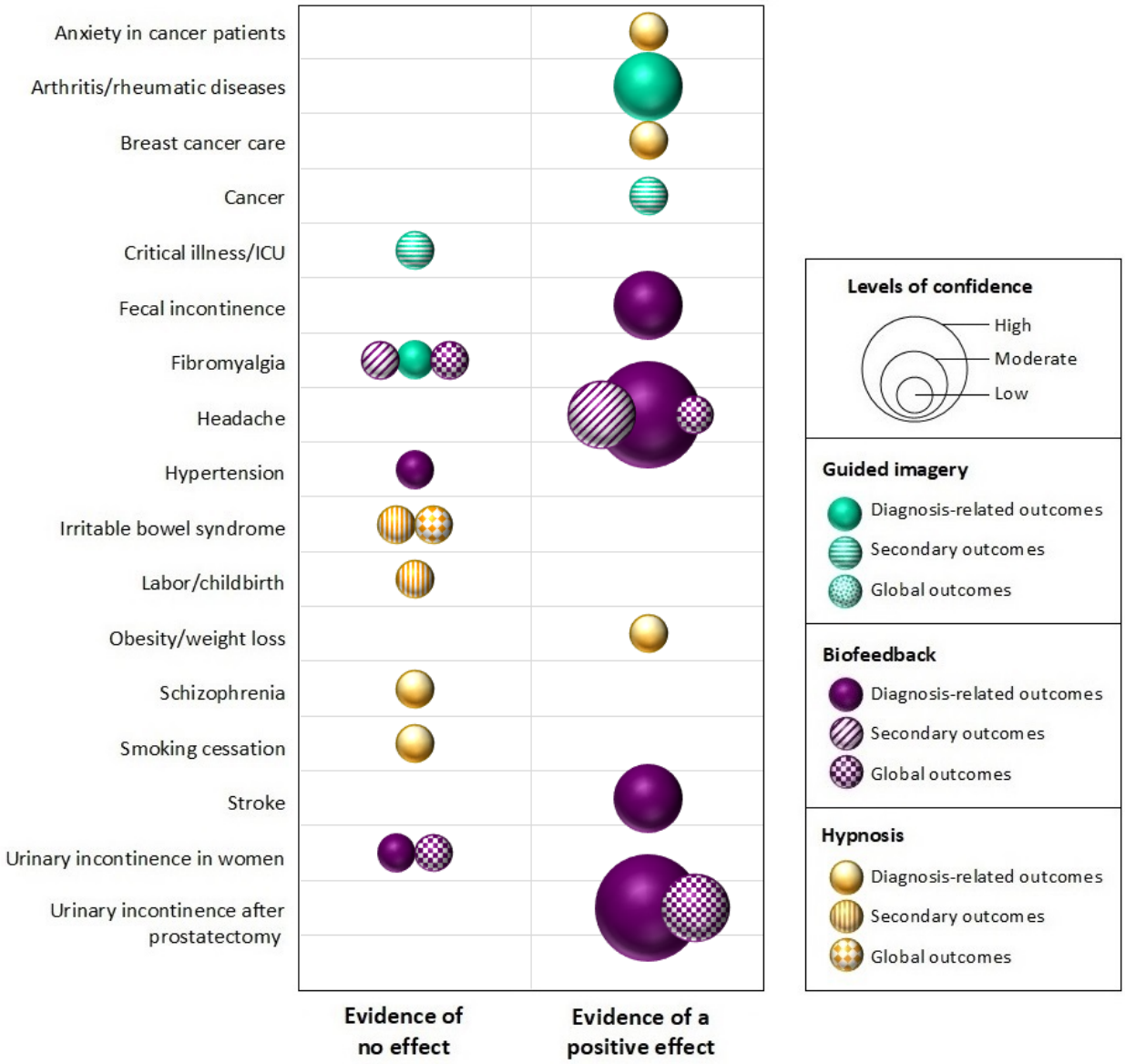
The only other intervention for which there was evidence of effectiveness supported by at least moderate level confidence was guided imagery in the treatment of patients with arthritis or other rheumatic diseases (Figure 6).

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 approaches[57] 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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APPENDIX A. SEARCH STRATEGIES

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Date Searched: March 14, 2018
Searched by: Robin Paynter, MLIS

	Searches	Results
1	"Imagery (Psychotherapy)"/	1528
2	(((guided or relaxation or reverie) adj3 (imagery or therapy)) or (mind adj2 body) or "Katathym-imaginative Psychotherapy").tw,kf.	10066
3	or/1-2	11235
4	biofeedback, psychology/ or neurofeedback/	7426
5	(biofeedback or neurofeedback).tw,kf.	7121
6	or/4-5	10378
7	hypnosis, anesthetic/ or hypnosis/	9135
8	(hypnosis or hypnotherap* or self-hypno*).tw,kf.	8400
9	or/7-8	11593
10	pain/ or pain management/ or abdominal pain/ or abdomen, acute/ or acute pain/ or arthralgia/ or shoulder pain/ or back pain/ or failed back surgery syndrome/ or low back pain/ or breakthrough pain/ or cancer pain/ or chest pain/ or angina pectoris/ or angina, unstable/ or angina, stable/ or chronic pain/ or earache/ or eye pain/ or facial pain/ or toothache/ or flank pain/ or glossalgia/ or headache/ or slit ventricle syndrome/ or labor pain/ or mastodynia/ or metatarsalgia/ or morton neuroma/ or musculoskeletal pain/ or myalgia/ or pelvic girdle pain/ or neck pain/ or neuralgia/ or neuralgia, postherpetic/ or piriformis muscle syndrome/ or pudendal neuralgia/ or sciatica/ or nociceptive pain/ or visceral pain/ or pain, intractable/ or pain, postoperative/ or phantom limb/ or pain, procedural/ or pain, referred/ or pelvic pain/ or dysmenorrhea/ or renal colic/	359439
11	(pain* or angina or appendicitis or arthralgia* or arthrit* or "broken bone*" or dysmenorrhea* or earache* or endometriosis or fasciitis or fibromyalgia* or "frozen shoulder" or glossalgia* or gout* or headache* or lupus or mastodynia or metatarsalgia* or neuroma* or migraine* or myalgia* or neuralgia* or neuropath* or nociceptive or osteoarthriti* or pancreatitis* or "phantom limb" or postamputation* or post-amputation* or "renal colic" or sciatica* or shingles or "sickle cell" or "slipped disc" or toothache*).tw,kf.	1185918
12	or/10-11	1275970
13	and/3,12	1520
14	limit 13 to (meta analysis or systematic reviews)	192
15	and/6,12	1951
16	limit 15 to (meta analysis or systematic reviews)	182
17	and/9,12	1843
18	limit 17 to (meta analysis or systematic reviews)	144
19	mental health/ or mental disorders/ or anxiety disorders/ or agoraphobia/ or anxiety, separation/ or neurocirculatory asthenia/ or neurotic disorders/ or obsessive-compulsive disorder/ or hoarding disorder/ or panic disorder/ or phobic disorders/ or phobia, social/ or "bipolar and related disorders"/ or bipolar disorder/ or "disruptive, impulse control, and conduct disorders"/ or firesetting behavior/ or gambling/ or trichotillomania/ or dissociative disorders/ or multiple personality disorder/ or elimination disorders/ or encopresis/ or enuresis/ or diurnal enuresis/ or nocturnal	1099654

	enuresis/ or "feeding and eating disorders"/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or "feeding and eating disorders of childhood"/ or female athlete triad syndrome/ or food addiction/ or night eating syndrome/ or pica/ or mood disorders/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or premenstrual dysphoric disorder/ or seasonal affective disorder/ or cyclothymic disorder/ or motor disorders/ or neurocognitive disorders/ or amnesia/ or alcoholic korsakoff syndrome/ or amnesia, anterograde/ or amnesia, retrograde/ or amnesia, transient global/ or cognition disorders/ or auditory perceptual disorders/ or huntington disease/ or cognitive dysfunction/ or consciousness disorders/ or delirium/ or emergence delirium/ or dementia/ or aids dementia complex/ or alzheimer disease/ or aphasia, primary progressive/ or primary progressive nonfluent aphasia/ or creutzfeldt-jakob syndrome/ or dementia, vascular/ or dementia, multi-infarct/ or diffuse neurofibrillary tangles with calcification/ or frontotemporal lobar degeneration/ or frontotemporal dementia/ or "pick disease of the brain"/ or kluver-bucy syndrome/ or lewy body disease/ or dyslexia, acquired/ or alexia, pure/ or neurodevelopmental disorders/ or "attention deficit and disruptive behavior disorders"/ or attention deficit disorder with hyperactivity/ or conduct disorder/ or communication disorders/ or social communication disorder/ or speech sound disorder/ or developmental disabilities/ or intellectual disability/ or learning disorders/ or dyscalculia/ or dyslexia/ or specific learning disorder/ or motor skills disorders/ or mutism/ or reactive attachment disorder/ or stereotypic movement disorder/ or tic disorders/ or tourette syndrome/ or paraphilic disorders/ or exhibitionism/ or "fetishism (psychiatric)"/ or masochism/ or pedophilia/ or sadism/ or transvestism/ or voyeurism/ or personality disorders/ or antisocial personality disorder/ or borderline personality disorder/ or compulsive personality disorder/ or dependent personality disorder/ or histrionic personality disorder/ or hysteria/ or paranoid personality disorder/ or passive-aggressive personality disorder/ or schizoid personality disorder/ or schizotypal personality disorder/ or "schizophrenia spectrum and other psychotic disorders"/ or affective disorders, psychotic/ or capgras syndrome/ or delusional parasitosis/ or morgellons disease/ or paranoid disorders/ or psychotic disorders/ or psychoses, substance-induced/ or psychoses, alcoholic/ or schizophrenia/ or schizophrenia, catatonic/ or schizophrenia, disorganized/ or schizophrenia, paranoid/ or shared paranoid disorder/ or sexual dysfunctions, psychological/ or dyspareunia/ or erectile dysfunction/ or gender dysphoria/ or premature ejaculation/ or "sexual and gender disorders"/ or vaginismus/ or sleep wake disorders/ or dyssomnias/ or sleep deprivation/ or sleep disorders, circadian rhythm/ or jet lag syndrome/ or sleep disorders, intrinsic/ or "disorders of excessive somnolence"/ or hypersomnolence, idiopathic/ or kleine-levin syndrome/ or narcolepsy/ or cataplexy/ or restless legs syndrome/ or "sleep initiation and maintenance disorders"/ or parasomnias/ or nocturnal paroxysmal dystonia/ or rem sleep parasomnias/ or rem sleep behavior disorder/ or sleep paralysis/ or sleep arousal disorders/ or night terrors/ or somnambulism/ or sleep bruxism/ or sleep-wake transition disorders/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or factitious disorders/ or munchausen syndrome/ or munchausen syndrome by proxy/ or hypochondriasis/ or neurasthenia/ or substance-related disorders/ or alcohol-related disorders/ or alcohol amnestic disorder/ or alcohol withdrawal delirium/ or alcoholic intoxication/ or alcoholism/ or binge drinking/ or wernicke encephalopathy/ or amphetamine-related disorders/ or cocaine-related disorders/ or inhalant abuse/ or marijuana abuse/ or "marijuana use"/ or neonatal abstinence syndrome/ or opioid-related disorders/ or morphine dependence/ or opium dependence/ or phencyclidine abuse/ or substance abuse, intravenous/ or substance abuse, oral/ or substance withdrawal syndrome/ or "tobacco use disorder"/ or "trauma and stressor related disorders"/ or adjustment disorders/ or stress disorders, traumatic/ or battered child syndrome/ or combat disorders/ or psychological trauma/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/	

20	("mental health" or "mental* ill*" or "mental disorder*" or "anxiety disorder*" or "agoraphobia" or neurotic or neurosis or neuroses or obsessive-compulsive or hoarding or "panic disorder" or "phobic disorder*" or "bipolar disorder" or manic-depress* or "conduct disorder*" or "firesetting behavior" or gambling or "dissociative disorder*" or "multiple personality disorder" or "elimination disorder*" or encopresis or enuresis or "eating disorder*" or "anorexia nervosa" or "binge-eating disorder" or "bulimia nervosa" or "food addiction" or "mood disorder*" or "depressive disorder" or "post-partum depression" or "major depression" or "dysthymic disorder" or "premenstrual dysphoric disorder" or "seasonal affective disorder" or "cyclothymic disorder" or "motor disorder*" or "neurocognitive disorder*" or "amnesia" or "cognition disorder*" or "auditory perceptual disorder*" or "huntington* disease" or "cognitive dysfunction" or "consciousness disorder*" or delirium or dementia* or "alzheimer* disease" or aphasia or "creutzfeldt-jakob syndrome" or "kluver-bucy syndrome" or "lewy body disease" or dyslexia or "neurodevelopmental disorder*" or "attention deficit and disruptive behavior disorder*" or "attention deficit disorder" or "ADD" or "attention deficit disorder with hyperactivity" or ADHD or "communication disorder*" or "speech sound disorder" or "developmental disabilit*" or "intellectual disabilit*" or "learning disorder*" or "reactive attachment disorder" or "tic disorder*" or "tourette* syndrome" or "paraphilic disorder*" or exhibitionism or fetishism or masochism or pedophilia or sadism or transvest* or voyeuris* or "personality disorder*" or hysteria or schizophreni* or "psychotic disorder*" or "affective disorder*" or "paranoid disorder*" or psychoses or "sexual dysfunction*" or dyspareunia or "erectile dysfunction" or "gender dysphoria" or "premature ejaculation" or "sexual* disorder*" or "gender disorder*" or vaginismus or "sleep wake disorder*" or dyssomnia* or "sleep disorder*" or "jet lag syndrome" or "excessive somnolence" or hypersomnolence or narcolep* or cataplex* or "restless legs syndrome" or parasomnia* or "nocturnal paroxysmal dystonia" or "rem sleep behavior disorder" or "sleep paralysis" or "sleep arousal disorder*" or "night terror*" or somnambulism or "sleep bruxism" or "sleep-wake transition disorder*" or "somatoform disorder*" or "body dysmorphic disorder*" or "conversion disorder" or "factitious disorder*" or "munchausen syndrome" or hypochondriasis or neurasthenia or "substance-related disorder*" or substance-abuse or drug-abuse or "alcohol-related disorder*" or alcohol-abuse or alcoholism or "alcohol withdrawal delirium" or "binge drinking" or "amphetamine-related disorder*" or amphetamine-abuse or methamphetamine-abuse or "cocaine-related disorders" or cocaine-abuse or "inhalant abuse" or "marijuana abuse" or "opioid-related disorder*" or opioid-abuse or opiate-abuse or morphine-dependence or morphine-abuse or opium-dependence or phencyclidine-abuse or "substance withdrawal syndrome" or "tobacco use disorder" or "adjustment disorder*" or "stress disorder*" or PTSD or "combat disorder*" or "psychological trauma").tw,kf.	888894
ESP21	or/19-20	1427346
22	and/3,21	1958
23	limit 22 to (meta analysis or systematic reviews)	155
24	and/6,21	1576
25	limit 24 to (meta analysis or systematic reviews)	114
26	and/9,21	2636
27	limit 26 to (meta analysis or systematic reviews)	92

Ovid EBM Reviews - Cochrane Database of Systematic Reviews 2005 to March 21, 2018
Date Searched: March 27, 2018
Searched by: Robin Paynter, MLIS

#	Searches	Results
1	((guided adj3 (imagery or meditation* or visuali?ation*)) or mind-body or "Katathym-imaginative Psychotherapy").ti,ab.	9
2	(biofeedback* or neurofeedback* or (autonomic* adj3 train*)).ti,ab.	24
3	(hypnosis or hypnotherap* or posthypnot* or post-hypnot* or self-hypno* or auto-hypno* or autohypno*).ti,ab.	26
4	or/1-3	51

Ovid PsycINFO 1806 to March Week 3 2018
Date Searched: March 27, 2018
Searched by: Robin Paynter, MLIS

1	Guided Imagery/	711
2	((guided adj3 (imagery or meditation* or visuali?ation*)) or mind-body or (imagery adj3 therap*) or "Katathym-imaginative Psychotherapy").tw,id.	6304
3	biofeedback, psychology/ or neurofeedback/	1321
4	(biofeedback* or neurofeedback* or (autonomic* adj3 train*)).tw,id.	6508
5	hypnosis/ or autohypnosis/ or hypnotherapy/	10915
6	(hypnosis or hypnotherap* or posthypnot* or post-hypnot* or self-hypno* or auto-hypno* or autohypno*).tw,id.	15548
7	or/1-6	29722
8	limit 7 to ("0830 systematic review" or 1200 meta analysis)	209
9	remove duplicates from 8	209

* * * * * * * * *

EBSCOhost CINAHL Plus with Full Text
Date searched: March 28, 2018
Searched by: Robin Paynter, MLIS

#	Search	Result
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6 **Limiters** - Exclude MEDLINE records; **Publication Type**: Meta Analysis, Systematic Review	205
S6	TI (hypnosis OR hypnotherap* OR hypno-therap* OR posthypnot* OR post-hypnot* OR self-hypno* OR autohypno* OR auto-hypno*) OR AB (hypnosis OR hypnotherap* OR hypno-therap* OR posthypnot* OR post-hypnot* OR self-hypno* OR autohypno* OR auto-hypno*)	1,950
S5	(MH "Hypnosis") OR (MH "Hypnosis, Anesthetic") OR (MH "Hypnosis (Iowa NIC)") OR (MH "Posthypnotic Suggestion")	2,611
S4	TI (biofeedback* OR bio-feedback* OR neurofeedback* OR neuro-feedback* OR (autonomic* N3 train*)) OR AB (biofeedback* OR bio-feedback* OR neurofeedback* OR neuro-feedback* OR (autonomic* N3 train*?))	2,428

S3	(MH "Biofeedback") OR (MH "Biofeedback (Iowa NIC)")	3,170
S2	TI ((guided N3 (imagery OR meditation* OR visuali#ation*)) OR mind-body OR "imagery N3 therap*" OR "Katathym-imaginative Psychotherapy") OR AB ((guided N3 (imagery OR meditation* OR visuali#ation*)) OR mind-body OR "imagery N3 therap*" OR "Katathym-imaginative Psychotherapy")	2,515
S1	(MH "Guided Imagery") OR (MH "Simple Guided Imagery (Iowa NIC)")	2,364

* * * * * * * *

Epistemonikos (https://www.epistemonikos.org)
Date Searched: March 28, 2018
Searched by: Robin Paynter, MLIS

(Title, abstract) "guided imagery" OR "guided meditation*" OR "guided visualization*" OR "guided visualisation*" or mind-body or "mind body" or "Katathym-imaginative Psychotherapy"
(Title, abstract) biofeedback* OR neurofeedback* OR "autonomic* train*"
(Title, abstract) hypnosis OR hypnotherap* OR hypno-therap* OR posthypnot* OR post-hypnot* OR self-hypno* OR auto-hypno* OR autohypno*

Limit: publication type = systematic review

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to September 24, 2018
Date Searched: September 25, 2018
Searched by: Robin Paynter, MLIS

#	Searches	Results
1	"Imagery (Psychotherapy)"/	1598
2	((guided adj3 (imagery or meditation* or visuali!ation*)) or (autogenic* adj3 train*) or (imagery adj3 therap*) or "integrative restoration" or (irest not "international reading speed") or "Katathym-imaginative Psychotherapy" or "mental practice" or "mental rehearsal" or "mind-body" or "yoga nidra").tw,kf.	4545
3	biofeedback, psychology/ or neurofeedback/	7576
4	((autonomic* adj3 train*) or biofeedback* or bio-feedback* or neurofeedback* or neuro-feedback* or neurotherap* or neuro-therap*).tw,kf.	8149
5	hypnosis, anesthetic/ or hypnosis/	9224
6	(autohypno* or auto-hypno* or hypnosis or hypnot* or hypnotherap* or hypno-therap* or posthypnot* or post-hypnot* or selfhypno* or self-hypno*).tw,kf.	21907
7	or/1-6	39811
8	limit 7 to (meta analysis or systematic reviews)	1538
9	(adolescent/ or exp child/ or exp infant/) not exp adult/	1762065
10	8 not 9	1417
11	Meta-Analysis as Topic/	16427
12	meta analy$.tw.	133311
13	metaanaly$.tw.	1866
14	Meta-Analysis/	92394
15	(systematic adj (review$1 or overview$1)).tw.	127604
16	exp Review Literature as Topic/	10064

17	or/11-16	239570
18	cochrane.ab.	63762
19	embase.ab.	68016
20	(psycinfo or psychinfo or psyclit or psychlit).ab.	25518
21	(cinahl or cinhal).ab.	21693
22	science citation index.ab.	2806
23	bids.ab.	463
24	cancerlit.ab.	622
25	or/18-24	111651
26	reference list$.ab.	15634
27	bibliograph$.ab.	16048
28	hand-search$.ab.	6019
29	relevant journals.ab.	1063
30	manual search$.ab.	3845
31	or/26-30	38166
32	selection criteria.ab.	27412
33	data extraction.ab.	16815
34	or/32-33	42134
35	Review/	2430793
36	and/34-35	28180
37	Comment/	733437
38	Letter/	1000623
39	Editorial/	468641
40	animal/	6269186
41	human/	17289997
42	40 not (40 and 41)	4464396
43	or/37-39,42	6062191
44	17 or 25 or 31 or 36	288530
45	44 not 43	273772
46	and/7,45	1285
47	or/10,46	1727
48	remove duplicates from 47	1693

APPENDIX B. STUDY SELECTION

Inclusion codes, code definitions, and criteria

1. Is the full-text of the article in English?
   Yes " Proceed to 2.
   No " STOP. **Code X1** *(Non-English language publication).*

2. Does the population include adults (aged 18+) with a specified health condition?

   Yes " Proceed to 3.
   No " STOP. **Code X2** *(Excluded population)*
   Note: a study that includes both children and adults may be included if it represents the best or only evidence for a particular health condition.

3. Does the intervention include guided imagery, biofeedback, or hypnosis, and report results specific to the intervention? Studies of guided imagery, biofeedback, or hypnosis as an adjunct therapy that report the additional effects of the intervention, compared with a study arm containing the primary therapy by itself, are included.

   Yes " Proceed to 4.

   Guided imagery:
   Include:
   - autogenic training
   - guided meditation
   - integrative restoration (iRest)
   - Katathym-imaginative Psychotherapy
   - mental imagery
   - mental practice
   - mental rehearsal
   - motor imagery
   - nightmare rescripting
   - yoga Nidra

   Exclude: virtual reality; mirror therapy

   Biofeedback: also “neurofeedback,” and “neurotherapy”
   Include: interventions that generate physiological values or data points that are fed back to the user.
   Exclude: Studies of biofeedback as part of a complex or multicomponent intervention.

   Hypnosis: also “hypnotherapy”.

   No " STOP. **Code X3** *(Not relevant to topic)*

4. Is the study design a systematic review or meta-analysis that includes controlled clinical trials (either randomized or non-randomized) with guided imagery, biofeedback, or hypnosis intervention as its main focus? Reviews that do not conduct a comprehensive

search (*eg,* only one electronic database), or do not assess study quality using validated criteria are excluded. Good-quality meta-reviews are included.

Yes " Proceed to 5.
No " STOP. **Code X4** (*Excluded study design or publication type)*

Exclude: Narrative or non-systematic review, critical review, scoping review, opinion/editorial, or primary study.

B code instructions: Mark any excludes that we should reference later B
Examples:
B-X3 – Narrative review with good background
B-X3 – May be useful for discussion

5. Indicate the intervention type by entering the KQ#, using multiple KQ#s as needed:
   a. Guided imagery: **KQ1**.
   b. Biofeedback: **KQ2.**
   c. Hypnosis: **KQ3.**

6. Indicate the population by entering health condition *eg,* "KQ2 - Fibromyalgia"

APPENDIX C. ASSESSMENT OF CONFIDENCE IN THE EVIDENCE FROM SYSTEMATIC REVIEWS OF GUIDED IMAGERY, BIOFEEDBACK, AND HYPNOSIS

Table 5. Assessment of confidence in the evidence on guided imagery

Medical condition/ target population	**Outcome category**	**Sample size** *1: <=100 2: 100-500 3: 500+*	**Consistency** *0: No major flaw -1: Serious inconsistency*	**Directness** *0: No major flaw -1: Limited applicability*	**Overall risk of bias** *0: Unclear/Low ROB -1: High ROB*	**Sum of values: Confidence rating** *≤0: Insufficient 1: Low 2: Moderate 3: High*
Anxiety[16]	Diagnosis-related	1	0	0	-1	Insufficient
	Secondary	1	0	0	-1	Insufficient
	Global	---	---	---	---	---
Arthritis/ rheumatic disease[20]	Diagnosis-related	2	0	0	0	Moderate
	Secondary	1	0	0	0	Low
	Global	1	0	0	0	Low
Cancer[23]	Diagnosis-related	2	0	0	-1	Low
	Secondary	2	0	0	-1	Low
	Global	1	0	0	-1	Insufficient
Cardiac surgery[25]	Diagnosis-related	2	-1	0	0	Low
	Secondary	2	-1	0	0	Low
	Global	---	---	---	---	---
Critical illness/ ICU[27]	Diagnosis-related	3	-1	0	-1	Low
	Secondary	3	-1	0	-1	Low
	Global	---	---	---	---	---
Fibromyalgia[3]	Diagnosis-related	2	-1	0	0	Low
	Secondary	2	0	0	-1	Low
	Global	1	-1	0	0	Insufficient
Headache[42] 7 trials (N=400)	Diagnosis-related	2	0	-1	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Insomnia[34]	Diagnosis-related	2	-1	0	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
	Diagnosis-related	2	0	-1	0	Low

Medical condition/ target population	**Outcome category**	**Sample size** *1: <=100 2: 100-500 3: 500+*	**Consistency** *0: No major flaw -1: Serious inconsistency*	**Directness** *0: No major flaw -1: Limited applicability*	**Overall risk of bias** *0: Unclear/Low ROB -1: High ROB*	**Sum of values: Confidence rating** *≤0: Insufficient 1: Low 2: Moderate 3: High*
Menstrual disorders[39]	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Musculoskeletal pain[43]	Diagnosis-related	2	0	-1	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Parkinson's[44]	Diagnosis-related	1	0	0	0	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Stroke[49]	Diagnosis-related	2	-1	0	0	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---

Abbreviations: CCT = Controlled clinical trial, GI = Guided imagery, ICU = Intensive care unit; ITT = Intention-to-treat; LOS = length of stay; MI = motor imagery; ROB = risk of bias, RCT = Randomized controlled trial; TTH = tension-type headache

Table 6. Assessment of confidence in the evidence on biofeedback

Medical condition or target population N controlled trials (N combined participants)	**Outcome category**	**Sample size** *1: <=100 2: 100-500 3: 500+*	**Consistency** *0: No major flaw -1: Serious inconsistency*	**Directness** *0: No major flaw -1: Limited applicability*	**Overall risk of bias** *0: Unclear or Low ROB -1: High ROB*	**Sum of values: confidence rating** *≤0: Insufficient 1: Low 2: Moderate 3: High*
Balance/Gait training[15] 8 (N=243)	Diagnosis-related	2	-1	0	0	Low
	Secondary	1	-1	0	0	Insufficient
	Global	1	0	0	0	Low
Bell's Palsy[21] 4 (N=118)	Diagnosis-related	2	-1	-1	0	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Chronic ideopathic constipation[26] 17 (N=931)	Diagnosis-related	1	0	0	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Dysphagia[29] 5 (N=141)	Diagnosis-related	1	-1	0	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Fecal incontinence[30] 12 (N=approx. 350)	Diagnosis-related	2	0	0	0	Moderate
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Fibromyalgia[31] 7 (N=321)	Diagnosis-related	2	0	0	-1	Low
	Secondary	2	0	0	-1	Low
	Global	2	0	0	-1	Low
Headache[13] 94 (N=3500+)	Diagnosis-related	3	0	0	0	High
	Secondary	2	0	0	0	Moderate
	Global	1	0	0	0	Low
Hypertension[32] 36 (N=1,660)	Diagnosis-related	2	0	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Intradialytic hypotension[33] 8 (N=716)	Diagnosis-related	2	0	0	-1	Low
	Secondary	1	-1	0	-1	Insufficient
	Global	2	-1	0	-1	Insufficient
	Diagnosis-related	1	0	-1	0	Insufficient

Medical condition or target population N controlled trials (N combined participants)	**Outcome category**	**Sample size** *1: <=100 2: 100-500 3: 500+*	**Consistency** *0: No major flaw -1: Serious inconsistency*	**Directness** *0: No major flaw -1: Limited applicability*	**Overall risk of bias** *0: Unclear or Low ROB -1: High ROB*	**Sum of values: confidence rating** *≤0: Insufficient 1: Low 2: Moderate 3: High*
Knee osteoarthritis/Gait retraining[36] 1 (N=56)	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Labor/childbirth[37] 4 (N=186)	Diagnosis-related	2	-1	-1	0	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Raynaud's[46] 10 (N=531)	Diagnosis-related	2	-1	-1	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Sleep bruxism[22] 6 (N=126)	Diagnosis-related	1	-1	0	-1	Insufficient
	Secondary	1	-1	0	-1	Insufficient
	Global	---	---	---	---	---
Stroke[14] 18 (N=429)	Diagnosis-related	2	0	0	0	Moderate
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Urinary incontinence in women[51] 24 trials (N=1,583)	Diagnosis-related	3	-1	0	-1	Low
	Secondary	2	-1	0	-1	Insufficient
	Global	2	0	0	-1	Low
Urinary incontinence after prostatectomy[50] 13 (N=1,108)	Diagnosis-related	3	0	0	0	High
	Secondary	---	---	---	---	---
	Global	2	0	0	0	Moderate

Abbreviations: ROB = risk of bias

Table 7. Assessment of confidence in the evidence on hypnosis

Medical condition or target population	**Outcome category**	**Sample size** *1: <=100 2: 100-500 3: 500+*	**Consistency** *0: No major flaw -1: Serious inconsistency*	**Directness** *0: No major flaw -1: Limited applicability*	**Overall risk of bias** *0: Unclear/Low ROB -1: High ROB*	**Sum of values: Confidence rating** *≤0: Insufficient 1: Low 2: Moderate 3: High*
Anxiety[17]	Diagnosis-related	2 (14 trials, N=653)	0	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Anxiety, cancer[18]	Diagnosis-related	3 (20 trials, N=878)	-1	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Anxiety, medical procedures[19]	Diagnosis-related	3 (18 trials, N=968)	-1	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Breast cancer care[24]	Diagnosis-related	3 (13 trials, N=1,357)	-1	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Fibromyalgia[3]	Diagnosis-related	1 (2 trials, N=95)	0	0	-1	Insufficient
	Secondary	1 (2 trials, N=95)	0	0	-1	Insufficient
	Global	1 (2 trials, N=95)	0	0	-1	Insufficient
Insomnia[34]	Diagnosis-related	2 (6 trials, N=218)	0	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Irritable bowel syndrome[35]	Diagnosis-related	2 (8 trials, N=464)	0	0	0	Moderate
	Secondary	2 (N≤314)	-1	0	0	Low
	Global	2 (5 trials, N=290)	-1	0	0	Low
Labor/childbirth[38] 9 (N=2,954)	Diagnosis-related	3 (8 trials, N=2916)	-1	-1	-1	Insufficient
	Secondary	3 (6 trials, N=2361)	-1	0	-1	Low
	Global	---	---	---	---	---
Obesity/weight loss[40]	Diagnosis-related	3 (10 trials, N=882)	-1	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Pain, disability-related[41]	Diagnosis-related	2 (10 trials, N=380)	-1	0	-1	Insufficient

Medical condition or target population	**Outcome category**	**Sample size** *1: <=100* *2: 100-500* *3: 500+*	**Consistency** *0: No major flaw* *-1: Serious inconsistency*	**Directness** *0: No major flaw* *-1: Limited applicability*	**Overall risk of bias** *0: Unclear/Low ROB* *-1: High ROB*	**Sum of values: Confidence rating** *≤0: Insufficient* *1: Low* *2: Moderate* *3: High*
	Secondary	2 (5 trials, N=180)	-1	0	-1	Insufficient
	Global	---	---	---	---	---
Postnatal depression[28]	Diagnosis-related	1 (1 trials, N=63)	0	0	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
PTSD[45]	Diagnosis-related	2 (5 trials, N=383)	-1	0	-1	Insufficient
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Schizophrenia[47]	Diagnosis-related	2 (3 trials, N=149)	0	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---
Smoking cessation[48]	Diagnosis-related	3 (11 trials, N=1,120)	-1	0	-1	Low
	Secondary	---	---	---	---	---
	Global	---	---	---	---	---

Abbreviations: ROB = risk of bias

APPENDIX D. FINDINGS OF INCLUDED SYSTEMATIC REVIEWS

Table 8. Effects of guided imagery by medical condition and outcome category

Medical condition/ target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Anxiety[16] 2 trials (N=44)	Diagnosis-related	Anxiety reduction (2 studies, N=44): Significant reduction within both T and C groups; between group significance NR	Unclear	Insufficient
	Secondary	Frequency of panic attacks (1 study, N=27): No significant decrease Psychovegetative complaints (1 study, N=27): Significant reduction within both T and C groups; between group significance NR	Unclear	Insufficient
	Global	---	---	---
Arthritis/rheumatic disease[20] 7 trials (N=207)	Diagnosis-related	Pain (2 studies, N=208): Significant reductions reported in all 5 studies. Qualitatively described only, no numeric effect sizes.	Positive	Moderate
	Secondary	Anxiety reduction (1 study, N=58): Significant reduction	Potential positive	Low
	Global	QOL (1 study, N=28): Significant increases in health-related QOL at week 12. Qualitatively described only, no numeric effect sizes. Mobility (2 studies, N=58): Significant improvements in mobility. Qualitatively described only, no numeric effect sizes.	Potential positive	Low
Cancer[23] 4 trials (N=199)	Diagnosis-related	Nausea/vomiting (2 studies, N=90): No effect. Comfort/Experience during radiation/chemo (3 studies, N=143): Significant improvement in comfort (P<0.05); Significantly more positive chemo experience (P<.0001)	Potential positive	Low
	Secondary	Anxiety/depression (2 studies, N=116): significant benefit	Positive	Low
	Global	QOL (1 study, N=56) significant benefit (P<0.01)	Unclear	Insufficient
Cardiac surgery[25] 6 trials (N=433)	Diagnosis-related	Pain (5 studies, N=355): Significant reduction found in 3 of 5 studies. Mixed findings overall. LOS (4 studies, N=304): Significant reduction found in 2 of 4 studies. Mixed findings overall.	Potential positive	Low
	Secondary	Anxiety reduction during pre- and post-op (5 studies): Significant reduction (P<0.05) Feeling of calm (1 study, N=25): significant benefit (P<.01). Fatigue (2 studies): reduced Sleep (2 studies): enhanced Anxiety/tension (6 studies, N=433): Significant benefit in 4 of 6 studies.	Potential positive	Low
	Global	---	---	---

Medical condition/ target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Critical illness/ICU[27] 10 trials (N=1363)	Diagnosis-related	Pain (6 studies, N=413): Significant reduction in 3 studies; non-significant reduction in 2 studies; no change in 1 study. Anxiety/tension (8 studies, N=1258): Significant reduction in 5 studies; non-significant reduction in 3 studies LOS (5 studies, N=1073): Significant reduction in 3 studies; non-significant reduction in 1 study; no change in 1 study Use of pain meds (2 studies, N=132): nonsignificant decrease Complications (N=156, 2 studies): no difference	Potential positive	Low
	Secondary	Non-significant reductions reported in depression, anger, fatigue, morbidity, pain medication; nonsignificant improvements seen in sleep quality, calm (N=814 for calm; N >100 for sleep, N <100 for depression, anger, morbidity). No change in depression, anger, in 1 study each. Patient satisfaction (3 studies, N=941): nonsignificant increase in 2 studies; no change in 1 study. Cost (2 studies, N=841): significant decrease in 1 study; no change in 1 study.	No effect	Low
	Global	---	---	---
Fibromyalgia[3] 4 trials (N=240)	Diagnosis-related	Pain (4 studies, N=224): 50%≤pain relief not significant: RD=0.05 (95% CI: -0.02 to 0.12), P=0.13; 30%≤pain relief favors GI: RD=0.15 (95% CI: 0.01 to 0.30), P=0.04 Mean pain intensity (4 studies, N=224): No difference: SMD=-0.55 (95% CI: -1.27 to 0.16), P=0.13 Only 1 of the 4 studies found significant benefit	No effect	Low
	Secondary	Psychological distress (2 studies, N=119): significantly favors GI: SMD=-0.49 (95% CI:-0.87 to -0.11), P=0.01. Heterogeneity was not significant: P=0.30 Acceptability (4 studies, N=232): Null effect: 0.01, (95% CI: -0.04 to 0.06), P=0.59. Heterogeneity not significant: p=0.42 Coping with pain (3 studies, N=169): Significantly favors GI: SMD=-0.39 (95% CI: -0.74 to -0.04), P=0.03. Heterogeneity not significant: P=0.27 Fatigue (1 study, N=64): Reduction not significant: SMD=-0.44 (95% CI: -0.94 to 0.06), P=0.08. Sleep problems: no data	Potential positive	Low
	Global	20%≤improvement of health-related QOL (2 studies, N=105): No effect: RD=0.09 (95% CI: -0.28 to 0.47), P=0.63. Heterogeneity P=0.04 Mean health-related QOL (2 studies, N=105): Not significant SMD=-0.28 (95% CI: -1.04 to 0.49), P=0.48. Heterogeneity P=0.06. One study (N=40) found marginally significant benefit w/ GI on QOL in both analyses; the other study found no benefit. Disability (1 study): No effect: SMD=-0.25 (95% CI: -0.74 to 0.24), P=0.32	Unclear	Insufficient

Medical condition/ target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Headache[42] 7 trials (N=400)	Diagnosis-related	Pain (N=400): Unclear effect in 3 studies (NR whether there was significant change from baseline), N=63. Significant improvement from baseline in 4 studies (N=337), but in these studies the effect of GI was equivalent to Hypnosis, and inferior to biofeedback.	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Insomnia[34] 6 trials (N=284)	Diagnosis-related	Sleep improvement: Mixed findings From MA (N ranging from 17 to 53 per analysis): No significant difference on most indicators (N awakenings during sleep; total sleep time; feeling refreshed in the morning; quality of sleep). Significant improvement on sleep onset latency in 1 study Sleep improvement within-group difference (5 studies, N=284): 3 studies found autogenic or guided hypnosis-like imagery training produced significant improvement in sleep from baseline to posttreatment. 2 studies found no significant improvement in any of the outcome measures.	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Menstrual disorders[39] 2 trials (N=250)	Diagnosis-related	Anxiety and depression: significant reduction (P<0.05)	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---
Musculoskeletal pain[43] 9 trials (N=325)	Diagnosis-related	Pain (9 RCTs, N=325): Significant benefit reported in 6 studies; nonsignificant benefit in 2 studies; no difference in 1 study.	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Parkinson's[44] 2 trials (N=60)	Diagnosis-related	Mobility (2 studies, N=60): Positive results on TUG test significant in only 1 study. Balance (1 study, N=23): no difference. UPDRS (1 study, N=23): More benefit in MI group, especially in the mental section Cognitive measure (clock drawing, stroop) in 1 study (N=23): No difference pre-post	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---

Medical condition/ target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Stroke[49] 17 trials (N=735)	Diagnosis-related	Balance (11 RCTs, N=430): SMD=0.81, 95% CI: [0.03 to 1.65], P=0.06, heterogeneity P<0.0001 Gait/walking ability (9 RCTs, N=389): SMD=0.69 [95% CI 0.38 to 1.00], P<0.00001; heterogeneity P=.04 Motor function of lower extremities (6 RCTs, N=307): SMD=0.84 [95% CI 0.45 to 1.22], P<0.0001; heterogeneity P=0.03.	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---

Abbreviations: CI = confidence interval; GI = guided imagery; ICU = intensive care unit; LOS = length of stay; MA = meta-analysis; MI = motor imagery; NR = not reported; UPDRS = Unified Parkinson's disease rating scale; P=p-value; QOL = quality of life; RCT = randomized controlled trial; RD = risk difference; SMD = standard mean difference; TUG = Timed Up and Go

Table 9. Effects of biofeedback by medical condition and outcome category

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Balance/Gait training[15] 8 (N=243)[f]	Diagnosis-related	Static steady-state balance outcomes: *Mediolateral - eyes open (4 RCTs, N=104):* Favors biofeedback (Hedges' g = 0.82), 95% CI (0.43 to 1.21). *Mediolateral - eyes closed (3 RCTs, N=84):* Favors biofeedback (Hedges' g = 0.57, 95% CI [0.14 to 0.99]). *Anterior-posterior sway - eyes open:* Favors biofeedback (Hedges' g = 0.55, 95% CI [0.01 to 1.10]) *Anterior-posterior sway - eyes closed:* Favors biofeedback (Hedges' g = 0.44, 95% CI [0.02 to 0.86]) Dynamic Steady-State Balance Measures: *Habitual gait speed:* No effect (Hedges' g = –0.19, 95% CI [–0.68 to 0.29]).	Potential Positive	Low
	Secondary	Studies which measured muscle strength, range of motion and physical activity did not report additional effects of WS training	Unclear	Insufficient
	Global	Health-related quality of life: favors biofeedback	Potential Positive	Low
Bell's Palsy[21] 4 (N=118)	Diagnosis-related	Facial symmetry, synkinesis, lip mobility: favors biofeedback	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Chronic idiopathic constipation[26] 17 (N=931)	Diagnosis-related	Symptom management – constipation score, improved, complete spontaneous bowel movements per week: Mixed findings	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Dysphagia[29] 5 (N=141)	Diagnosis-related	Swallow function (2 RCTs, N=51): No difference (MD=1.10, 95 CI [-1.69 to 3.89]) Hyoid displacement (3 RCTs, N=90): Favors biofeedback (MD=0.22cm, 95% CI [0.04 to -0.40], P=0.02). Dependency on tube feeding (2 RCTs, N=53): No difference (OR=3.19, 95% CI [0.16 to -62.72]).	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Fecal incontinence[30] 12 (N=approx. 350)[g]	Diagnosis-related	Remission rate (6 RCTs): Favors biofeedback	Positive	Moderate
	Secondary	---	---	---
	Global	---	---	---
Fibromyalgia[31] 7 (N=321}	Diagnosis-related	Pain intensity (7 RCTs, N=289): Favors biofeedback (g = 0.79, 95% CI [0.22 to1.36], P=0.006). Subgroup analyses revealed that only EMG-BFB and not EEG-BFB significantly reduced pain intensity in comparison to control groups (g = 0.86, 95% CI [0.11–1.62]). Long term pain intensity (2 RCTs, N=86): No difference (g = 0.86, 95% CI [−1.25–2.98], P=0.42).	Potential positive	Low
	Secondary	Sleep problems (2 RCTs, N=87): No difference (g = 0.23, 95% CI [−0.20 to 0.65], P=0.29). Depression (4 RCTs, N=181): No difference (g = 0.37, 95% CI [−0.44 to 1.18], P=0.37). Long term depression (3 RCTs, N=120): No difference (g = 0.8, 95% CI [−0.51 to 2.11], P=0.23). Fatigue (4 RCTs, N=163): No difference (g = 0.38, 95% CI [−0.46 to 1.08], P=0.43).	No effect	Low
	Global	Quality of life (4 RCTs, N=163): No difference (g = 0.62, 95% CI [−0.77 to 2.02], P=0.38). Long term quality of life (2 RCTs, N=68): No difference (g = 0.252, 95% CI [−2.94 to 7.98], P=0.37).	No effect	Low
Headache[13] 94 (N=3500+)	Diagnosis-related	Migraine reduction – frequency, duration, intensity: favors biofeedback Tension type headache reduction – frequency, duration, intensity: favors biofeedback	Positive	High
	Secondary	Medication intake: favors biofeedback Muscle tension: favors biofeedback Depression: favors biofeedback Anxiety: favors biofeedback	Positive	Moderate
	Global	Self-efficacy: favors biofeedback	Positive	Low
Hypertension[32] 36 (N=1,660)[c]	Diagnosis-related	Blood pressure: No benefit vs pharmacotherapy. Favors sham or non-specific behavioral interventions when combined with relaxation. (Unclear effect compared with behavioral or sham. Confidence level: Insufficient)	No effect	Low
	Secondary	--	---	---
	Global	---	---	---

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Intradialytic hypotension[33] 8 (N=716)[d]	Diagnosis-related	All-cause mortality (2 RCTs, N=104): Two deaths occurred in patients undergoing biofeedback hemodialysis (HD), when compared with 6 deaths among patients undergoing conventional HD. The pooled effect estimate did not rule out a beneficial or harmful effect of biofeedback dialysis (RR=0.37, 95% CI [0.07–2.01]). Intradialytic hypotension (6 RCTs, N=266): Favors biofeedback (RR=0.61, 95% CI [0.44–0.86]). Pre-dialysis systolic blood pressure (7 RCTs, N=203): No difference (MD = 3 mmHg, 95% CI [−2-7]). Post-dialysis systolic blood pressure (3 RCTs, N=77): Favors biofeedback (MD = 7 mmHg (95% CI [5–19], χ^2 = 10.52, P=0.005). However, statistical heterogeneity may have resulted from different follow-up times and patient characteristics.	Potential positive	Low
	Secondary	Pre- and post- dialysis sodium levels (3 RCTs, N=NR): No difference. Urea clearance (3 RCTs, N=130): No difference. Post-dialysis regional wall motion abnormalities (1 RCT, N=10): Favors biofeedback.	Unclear	Insufficient
	Global	Quality of Life (3 RCTs, N=140): Mixed findings.	Unclear	Insufficient
Knee osteoarthritis/Gait retraining[36] 1 (N=56)	Diagnosis-related	Pain: No difference at 3, 6, 9, 12 months. Self-reported knee function: Favors biofeedback at 3 months (MD=8.6, P=0.04), but not at 6 or 12 months.	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Labor/childbirth[37] 4 (N=186)	Diagnosis-related	Rates of assisted vaginal birth: No difference Caesarean section: No difference Augmentation of labor: No difference Use of pharmacotherapy for pain: No difference	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Raynaud's[46] 10 (N=531)	Diagnosis-related	Symptom frequency/intensity: Favors biofeedback	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Sleep bruxism[22] 6 (N=126)[e]	Diagnosis-related	First night's change in EMG episodes/hour (3 RCTs, N=65): No difference (MD=−5.05, 95% CI [−10.71 to 0.62]). Fifth night's change in EMG episodes/hour (3 RCTs, N=39): Favors biofeedback (MD=−7.18, 95% CI [−12.54 to −1.83]). EMG activity per hour (2 RCTs, N=26): Favors biofeedback.	Unclear	Insufficient
	Secondary	SB-related EMG activities (1 RCT, N=12): Favors biofeedback. Measurement of SB events – episodes and duration (1 RCT, N=24): Favors biofeedback. Pain (2 RCTs, N=26): No difference. Sleep quality (2 RCTs, N=35): No difference.	Unclear	Insufficient
	Global	--	---	---
Stroke[14] 18 (N=429)	Diagnosis-related	Lower limb activities (17 RCTs, N=417): Favors biofeedback (SMD=0.50, 95% CI [0.30 to 0.70]).	Positive	Moderate
	Secondary	---	---	---
	Global	---	---	---
Urinary incontinence in women[51] 22 trials (N=1,361 [biofeedback])[b]	Diagnosis-related	Self-reported symptomatic cure or improvement: *PFMT + BF versus PFMT (9 RCTs, N=604):* Favored PFMT + biofeedback to PFMT alone (RR=0.75, 95% CI: 0.66 to 0.86). However, there was significant heterogeneity in PFMT and subgroup analyses found no difference between groups between biofeedback and no biofeedback. *PFMT vs PFMT + feedback + biofeedback – cure vs no cure (1 RCT, N=152)*: No difference (OR=1.59, 95% CI:0.43 to 5.87) *PFMT + BF versus PFMT + feedback (2 RCTs, N=130):* No difference	No effect	Low

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
	Secondary	Number of leakage episodes in 24 hours: *PFMT vs PFMT + feedback + biofeedback – cure vs no cure (1 RCT, N=152)*: No difference (Z=1.04, P=0.30). *PFMT + BF versus PFMT + feedback (3 RCTs, N=267):* No difference Pelvic floor muscle function: *PFMT vs PFMT + feedback + biofeedback – repetitions, endurance, perineometry, modified Oxford Scale, number of fast contractions (1 RCT, N=152)*: Favored PFMT with feedback and BF group vs. PFMT alone. *PFMT + BF versus PFMT + feedback - % of subjects with increase on EMG assessment, ultrasound displacement, pressure perineometry, digital vaginal palpation, endurance (sitting, standing), amplitude EMG (4 RCTs, N=180):* Mixed findings. Frequency of micturition: *PFMT vs PFMT + feedback + biofeedback (1 RCT, N=152)*: No difference. *PFMT + BF versus PFMT + feedback (1 RCT, N=40):* No difference Symptom distress: *PFMT vs PFMT + feedback + biofeedback (1 RCT, N=152)*: No difference. *PFMT + BF versus PFMT + feedback (2 RCTs, N=150):* No difference Pad changes in 24 hours: *PFMT vs PFMT + feedback + biofeedback (1 RCT, N=152)*: No difference. Adherence to treatment: *PFMT vs PFMT + feedback + biofeedback (1 RCT, N=152)*: No difference. Patients' satisfaction with progress or outcome: *PFMT + BF versus PFMT + feedback (1 RCT, N=107):* No difference	Unclear	Insufficient
	Global	General and incontinence specific quality of life: *PFMT + BF versus PFMT (9 RCTs, N=497):* No difference *PFMT + BF versus PFMT + feedback (3 RCTs, N=201)*: No difference	No effect	Low
Urinary incontinence after prostatectomy[50] 13 (N=1,108)[a]	Diagnosis-related	Objective measurement of urinary incontinence improvement*:* Favors PFMT + biofeedback (immediate-, intermediate-, and long-term) vs pelvic floor muscle training alone (P=0.023, 0.002, and 0.017, respectively). Subjective measurement of urinary incontinence improvement: Favors PFMT + biofeedback (intermediate-, and long-term) vs pelvic floor muscle training alone (P=0.034 and 0.005, respectively). There were no significant immediate effects (P=0.108).	Positive	High

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
	Secondary	---	---	---
	Global	Quality of life: Favors PFMT + biofeedback (immediate- and intermediate-term) vs pelvic floor muscle training alone (P=0.003 and 0.11, respectively). There was no effect on long-term urinary incontinence (P=0.080).	Positive	Moderate

[a] Biofeedback with pelvic floor muscle training with or without electrical stimulation, [b] Biofeedback with pelvic floor muscle training (PFMT) with or without feedback, [c]Biofeedback alone or as an adjunct vs. pharmacotherapy, sham, or behavioral interventions, [d] Biofeedback hemodialysis vs conventional hemodialysis, [e] Biofeedback with swallow therapy,

Abbreviations: BF = biofeedback, CI = confidence interval; EMG = electromyograph; g = Hedge's g; MD = mean difference, NR = not reported; OR = odds ratio; P = p-value; PFMT = pelvic floor muscle training; RCT = randomized control trial; RR = risk ratio; SB = sleep bruxism; SMD = standard mean difference

Table 10. Effects of hypnosis by medical condition and outcome category

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Anxiety[17] 14 (N=653)	Diagnosis-related	Generalized anxiety: mixed results from 3 studies Trauma: mixed results mostly non-significant from 2 studies Phobic anxiety: mixed and positive findings from 6 studies Tests: mixed results from 3 studies	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---
Anxiety, cancer[18] 20 (N=878)	Diagnosis-related	Immediate effect on anxiety: Hedges' g: 0.70-1.41; P<0.01 Sustained effect on anxiety: Hedges' g: 0.61-2.77; P<0.01	Positive	Low
	Secondary	---	---	---
	Global	---	---	---
Anxiety, medical procedures[19] 10 (N=525 [anxiety])	Diagnosis-related	Anxiety intensity during and after medical procedure (5 studies, N=264): Significant difference, favors hypnosis (3 studies, N=206); not significant (2 studies, N=58)	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---
Breast cancer care[24] 13 (N=1,357)	Diagnosis-related	Pain (4 trials): consistent significant effect (P<0.05) Distress (8 trials): consistent significant effect (P<0.05) Fatigue (3 trials): consistent significant effect (P<0.05) Nausea/vomiting (1 trial): significant effect (P<0.001) Hot flashes (2 trials): consistent significant effect (P<0.05)	Positive	Low
	Secondary	---	---	---
	Global	---	---	---
Fibromyalgia[3] 5 (N=388)	Diagnosis-related	Pain (2 studies of hypnosis, N=75): pain relief≥50% significant (P=0.04); pain relief≥30% significant (P=0.005) Pain (2 studies of CBT + hypnosis, N=95): pain relief≥50% not significant (P=0.25); pain relief≥30% not significant (P>0.05) Disability (2 studies of CBT + hypnosis, N=95): No difference (P=0.85)	Unclear	Insufficient
	Secondary	Psychological distress (1 hypnosis study, N=59): nonsignificant reduction Psychological distress (2 studies of CBT + hypnosis, N=95): SMD=-0.50 (95% CI:-0.91 to -0.09) significant reduction P=0.02	Unclear	Insufficient
	Global	Health-related quality of life at end of treatment (1 hypnosis study, N=59): Not significant Health-related quality of life at end of treatment (2 studies of CBT + hypnosis, N=95): improvement≥20% RD=0.18 (95% CI: -0.01 to 0.38) not significant (P=0.07)	Unclear	Insufficient

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
Insomnia[34] 6 (N=218)	Diagnosis-related	Within group: Significant improvement in either from baseline to post-treatment (5 studies) Between group: Significantly more effective than comparator (4 studies); No difference (1 study); less effective than comparator (1 study)	Potential positive	Low
	Secondary	---	---	---
	Global	---	---	---
Irritable bowel syndrome[35] 8 (N=464)	Diagnosis-related	Adequate symptom relief at end of therapy: Favored treatment: RR=1.69 (95% CI: 1.14-2.51); P=0.009 Global gastrointestinal score at end of therapy: T group experienced greater reduction. SMD=-0.32 (95% CI: -0.56 to -0.08); P=0.008 Adequate symptom relief at long-term follow-up (1 study): Favored treatment. RR, 2.17 (95% CI: 1.22-3.87); P=0.008 Global gastrointestinal score at long-term follow-up (2 studies): No difference. SMD=-0.57 (-1.40 to 0.26); P=0.180	Potential positive	Moderate
	Secondary	Pain, diarrhea, constipation, bloating/distention, depression, anxiety: No difference at end of therapy	No effect	Low
	Global	Impaired health-related quality of life (N=290): No difference SMD=-0.56 (95% CI:-1.44 to 0.32); P=0.21	No effect	Low
Labor/childbirth[38] 9 (N=2,954)	Diagnosis-related	Use of pharmacological pain relief or anesthesia during labor and childbirth (8 studies, N=2916): Average RR=0.73, 95% CI: 0.57 to 0.94; Significantly less likely to use; Z=2.47 (P=0.014) Satisfaction with pain relief (2 trials, N=264): No effect for all except women who had water immersion births (1 trial, N=174) MD=0.52; 95% CI: 0.04 to 1.00 Sense of coping in labor (1 trial, N=420): MD=0.22; 95% CI: -0.14, 0.58. No difference (P=0.22). Spontaneous vaginal birth (6 studies, N=2361): No difference. Average RR=1.12; 95% CI: 0.96 to 1.32.	Unclear	Insufficient

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
	Secondary	Pain intensity: no difference in 2 of 3 trials Satisfaction with childbirth experience no difference in 2 of 3 trials (trial with significantly higher satisfaction: N=1,126, P=0.0023) No significant difference in any of the following (N:~400-2,800): breastfeeding at discharge; assisted vaginal birth; cesarean section; admission to NICU; Apgar score less than 7 at 5 minutes; use of epidural; preterm birth; length of labor; perineal trauma; induction of labor; augmentation of labor with oxytocin; primary postpartum hemorrhage; cost; need for postpartum blood transfusion; mother or newborn readmission Significant effect in 1 trial each: postnatal depressive symptoms; number of maternal days in hospital (>2 days after the birth)	No effect	Low
	Global	---	---	---
Obesity/weight loss[40] 10 studies/ 14 trials by Tx (N=882)	Diagnosis-related	Mean weight loss at post (14 trials, N=882): MWES=1.58 (SE 0.09; 95% CI 1.40 to 1.76); Significant effect (Z=17.56, P=0.001, two-tailed) Mean weight loss at follow-up (6 trials, N=185): MWES=0.88 (SE=0.18, 95% CI 0.53 to 1.23); Significant effect (Z=4.89, P=0.001, two-tailed) Mean weight loss with (7 post trials) vs without (7 post trials) adjunctive self-hypnosis: Significant effect for both (P≤0.001), but significantly greater effect for interventions including self-hypnosis (Q=19.24, df=1, P≤.001) Mean weight loss at follow-up for combined CBT & Hypnosis versus CBT (12 trials, N=602): MWES=0.80 (SE=0.09, 95% CI: 0.62 to 0.98); Significant effect (Z=8.89, P=0.001, two-tailed)	Positive	Low
	Secondary	---	---	---
	Global	---	---	---
Pain, disability-related[41] 10 (N=380)	Diagnosis-related	Absolute treatment effectiveness compared to no treatment or education only: medium weighted effect size = 0.53 (CI: 0.28 to 0.84) Compared to other cognitive-behavioral treatments: Not significant. Wide variation in the magnitude of individual effect sizes, including some positive findings	Unclear	Insufficient
	Secondary	Short-term psychological: Reduced symptoms of depression (d=1.19), and improved perceived control over pain (d=0.54) immediately following hypnotherapy. Long-term psychological: Small to medium non-significant effect size across individual psychological outcomes (3 to 6 months post-treatment)	Unclear	Insufficient
	Global	---	---	---
Postnatal depression[28] 1 (N=63)	Diagnosis-related	Risk of developing PND: The SR found no studies meeting their inclusion criteria.	Unclear	Insufficient

Condition/target population N controlled trials (N combined participants)	Outcome category	Findings	Summary of effect	Overall confidence
	Secondary	---	---	---
	Global	---	---	---
PTSD[45] 5 (N=383)	Diagnosis-related	PTSD symptoms post-intervention (4 RCTs, N=160): Favors hypnosis (d=1.17) PTSD symptoms 4-wk follow-up (3 RCTs, N=108): Favors hypnosis (d=1.58) PTSD symptoms 12 & 16-18-wk follow-up (2 RCTs, N=66): 12-wk favors hypnosis (d=0.93); 16-18 week favors hypnosis (d=2.44) PTSD symptoms 12-month follow-up (1 RCT, N=36): favors hypnosis (d=3.61) PTSD symptoms 2 years (1 RCT, N=226): favors hypnosis (d=0.66)	Unclear	Insufficient
	Secondary	---	---	---
	Global	---	---	---
Schizophrenia[47] 3 (N=149	Diagnosis-related	Mental state: nonsignificant differences	No effect	Low
	Secondary	---	---	---
	Global	---	---	---
Smoking cessation[48] 11 (N=1,120)	Diagnosis-related	Quit rates: Most studies did not detect significant differences at 6 months or longer	No effect	Low
	Secondary	---	---	---
	Global	---	---	---

Abbreviations: CBT = cognitive-behavioral therapy; CCT = controlled clinical trial; CI = confidence interval; d= Cohen's d; df = degrees of freedom; EMG = Electromyograph; HD = hemodialysis; MD = mean difference; MWES = mean weighted effect size; NICU = neonatal intensive care unit; P=p-value; PND = postnatal depression; PTSD = posttraumatic stress disorder; Q = q-value; RCT = randomized control trial; RD = risk difference; RR = risk ratio; SE = standard error; SR = systematic review; SMD = standard mean difference; Z = z-value

APPENDIX E. PEER REVIEWER COMMENTS AND AUTHOR RESPONSES

Rev #	Comment	Author Response
Are the objectives, scope, and methods for this review clearly described?		
1	Yes	Noted, thank you.
2	Yes	Noted, thank you.
3	No - unclear how more recent reviews were selected	Thank you. In the Methods section we describe the selection process as follows: when there were several qualified reviews of an intervention for the same health condition, we selected a single review based on its recency, methods, scope, and applicability.
4	Yes	Noted, thank you.
5	Yes	Noted, thank you.
6	Yes	Noted, thank you.
Is there any indication of bias in our synthesis of the evidence?		
1	Yes - Well bias is too strong a word--I would say no bias at all in the synthesis but some bias or at least excessive caution in how the results are presented in the narrative. Much more detail in my comments on this below.	Thank you. We have responded in the comments below.
2	Yes - (1) Should have included heart rate variability biofeedback (HRVB) in review of biofeedback. (2) As a result of (1), medical conditions and target populations listed in Table 3, page 23 that are responsive to HRVB were not found on Table 4, page 30 (e.g. Anxiety, Depression, IBS, Insomnia, muscular-skeletal Pain, PTSD to name a few). I believe that even if the findings of the literature search of HRVB showed No effect and Level of Confidence Unclear/Insufficient evidence, this would have been reported if HRVB had been considered at all.	Thank you. Heartrate variability biofeedback was captured by our search, however there was only 1 systematic review, and it did not meet inclusion criteria. We added a sentence to the Methods section of the paper noting the absence of this modality. We acknowledge limitations of the evidence map methodology – we have added more language about these limitations to the report and executive summary.
3	Yes - 1. There is a major concern in regard to the criticism that more blinded trials are needed. While blinding is critically important in drug trials, blinding in behavioral trials is often impossible and frequently ill-advised. Consider that blinding in drug trials is employed to control for the effects of expectancy on outcomes, as the mechanism of change is hypothesized to be the chemical action of the drug. In behavioral trials, mechanisms are psychological. In the case of hypnosis specifically, expectancy change is explicitly a mechanism of change (among others), which has been supported in the research literature. To blind patients to hypnosis would be to impair the mechanism of change, and thereby decrease efficacy. Also, how would be patients be blinded? Would the investigator not use the word “hypnosis” in the consent document (which could be considered unethical if the researcher really considered the intervention to be hypnosis)? Would the investigator not use the word “hypnosis” during the intervention? In that case, the trial would not be testing hypnosis, if would be testing some other intervention. Research indicates that when you do not label the intervention hypnosis, effect sizes decrease, again, biasing against the hypnosis intervention.	Thank you for bringing up this point. We have revised the paragraph in question (in Discussion) to reflect both sides of the debate in regard to blinding in CAM trials.

	Meta-analyses and reviews which include “hypnosis” interventions which do not use the term are therefore potentially biased against the efficacy of intervention. There is concern that such criticism about blinding is simply echoing conclusions drawn from previous, less than thoughtful, reviews. This review has an opportunity to be both more thoughtful and educated on the topic. To the extent that other behavioral interventions incorporate expectancy as a mechanism of change, these criticisms apply.	
4	Yes - Some studies have been overlooked; and by only using reviews, other valuable findings have been excluded. Additionally, myriad studies combine guided imagery with another method, or define the intervention as a combination, so we miss out on some good evidence. For instance, a lot of guided imagery begins with simple relaxation – it’s part of the guided imagery process. This is sometimes described by the authors as ‘relaxation plus guided imagery’, and I fear those studies may have been excluded.	Thank you. This will depend on how each systematic review defined guided imagery and chose to include/exclude studies. Systematic reviews that did not individually analyze the results by intervention were excluded unless the intervention was guided imagery combined with another modality and the comparator was guided imagery alone. We acknowledge the limitations of evidence mapping, including the potential to miss some good evidence given our reliance on systematic reviews and we have added more language about these limitations to the report and executive summary.
	One study which, under the criteria, would have been excluded, would be the Guarneri study out of Scripps, published in Military Medicine a few years ago, where the intervention was a combination of guided imagery and Healing Touch, two distinct techniques. Nonetheless, the study was strong and yielded exciting data: it had an ‘n’ of 123 Camp Pendleton Marines, between deployment, with moderate to severe symptoms of PTSD. As compared with standard care (which included individual psychotherapy, medication and EMDR,) these subjects showed robust improvement on several key symptoms, in the short span of 3 weeks (6 sessions). Given the fact that this was a military population in an RCT with a respectable number of subjects, who had unusual gains in a famously refractory condition, I think this combo is worth a mention, even as a footnote. If what we are after is practical solutions that work in real time, (and I know we all are,) isn’t this combo exactly what we want to know about, and test further with our vets?	Thank you. Individual RCTs would not have been captured in this paper given that we were searching for systematic reviews.
5	No	Noted, thank you.
6	No	Noted, thank you.
Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked?		
1	No	Noted, thank you.
2	Yes - Numerous articles reporting on effects of HRVB. I suggest re-doing the entire Biofeedback section using a literature search with keywords **"HRV biofeedback'**. Relatedly, for some unknown the searches for 'neurofeedback' and 'neurotherapy' did not yield the findings I would have expected it to report. Furthermore, I recommend pulling Biofeedback out	Thank you. Search terms for heartrate variability biofeedback, neurofeedback, and neurotherapy were included in our search. One systematic review on HRV occurred in the literature yield but did not meet inclusion criteria. Though citations on neurotherapy

	of ESP reporting as it is presently combined with Guided Imagery and Hypnosis and doing a separate report with Biofeedback alone.	occurred in the search yield, there were no systematic reviews that meet inclusion criteria. The search for neurofeedback yielded a number of citations, and the SRs included in the evidence map include this modality (see Table 4) The reason why guided imagery and hypnosis are combined with biofeedback in this report is because a requested was made by the operational partners at the VA for evidence maps of the three interventions in a single report.
3	No	Noted, thank you.
4	Yes - Yes, I believe so. See attached document for additional systematic reviews, as well as recent or notable individual studies. One area that may have been partially overlooked regards medical procedures, such as dialysis, ventilator weaning, needle sticks, chemo, radiation tx, general surgery, etc. Even where there are too few studies to generate a review, the findings – on ventilator weaning, for instance – are impressive. Benefits of imagery for post-op pain, blood loss, opioid and analgesic use, length of stay, bowel motility, pre- and post-op anxiety are also worth including – there's a lot. I have included several in my attached document. There are studies of guided imagery up-regulating immune function (not necessarily related to cancer – also re flus, colds, herpes, etc) that perhaps belong here as well. I also think there are significant benefits for enhancing performance, focus, mastery of tasks, physical competence in sport or rehab, that have important implications for our vets with neurodegenerative disease, injuries, stroke, TBI, limb loss, and severe anxiety. I've also included studies on smoking cessation and several unpublished papers and a chapter on imagery and PTSD. I just want to encourage you all to give guided imagery a second, more exhaustive (and perhaps exhausting!) look. :-)	Thank you for the list. As stated previously, primary studies would not have been captured by the evidence map format. The suggested systematic reviews you noted were captured by our search but did not meet our inclusion criteria. We acknowledge the limitations of evidence mapping, including the potential to miss some good evidence given our reliance on systematic reviews, and we have added more language about these limitations to the report and executive summary.
	ADDED AFTER PEER REVIEW BY EMAIL: This is a big P.S., discovered late, for which I apologize, but of some consequence to the committee's inquiry: I've begun working on a paper I'm giving later on in the year on the primal importance of guided imagery for managing separation anxiety, learned by humans from baby- and toddler-	Thank you for these suggestions. We examined the systematic review on attachment security priming, but determined it was not eligible for inclusion on the evidence map because the studies were conducted in healthy volunteer samples rather than targeting a specific health condition.

	hood, across all cultures, and how it's a built-in coping tool of great consequence to adults, especially regarding grief, trauma and any deep distress. It meant going through the psychodynamic attachment literature, something I haven't done in a while. And lo and behold, I found a major term for guided imagery I'd never run into, called ***attachment security priming.*** It talks about an element I've always inserted as the central healing element in the imagery I construct, so shame on me for not knowing the term. We are all in our silo's!! It turns out that security priming studies are all over the place, and it primarily consists of guided imagery that creates a sense of security similar to that induced by the presence of supportive others who provide love, comfort and security, termed 'attachment figures'. (Occasionally it's simple exposure to words, such as *love, hug, affection*, either subliminally or supra-liminally. Sometimes it's exposure to pictures showing these things. But 80% of recent studies ask participants to imagine such scenarios or relationships, or recall memories of experiencing being loved by such attachment figures – which is defined as *guided imagery or visualization.)* The studies using guided imagery yield the most powerful outcomes, in terms of improvements in mood, attitude toward new situations, death anxiety, aggression, compassion and depression. I discovered this in a literature review of security priming studies from the last 2 years, (106 articles), ***Attachment security priming: a systematic review*** by Omri Gillath and Gery Karantzas, part of a themed issue on Attachment in Adulthood, edited by Jeffry A Simpson and Gery Karantzas in Current Opinion in Psychology 2019, 25:86-95. See www.sciencedirect.com/. Anyway, late as it is, I felt it important to alert you to this newly discovered treasure trove of guided imagery studies. Hope you can include them in your inquiry. It gives guided imagery its due. I can't read enough of these articles, myself.	
5	Yes - **Van Doren, et al 2018, European Child & Adolescent Psychiatry**	Thank you. This systematic review did not meet our inclusion criteria because the studies were in children, and we were specifically searching for adult populations.
6	No	Notes, thank you.
Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.		
1	I have one major concern which runs throughout the document regarding the order in which conclusions are stated and summarized and what that communicates or does not communicate to the reader. Happy to discuss further. Overall I think the science here is excellent but I find the presentation of the results overly cautious with some potential to reinforce existing biases regarding these therapies.	Noted. Responses below.

1	**P3 Line 13**. I would list the positive finding regarding arthritis first and then the statement about the findings being mixed and the confidence low second. Clinicians will be reading looking for "where does it really work." If we bury this important info behind a statement which says "we don't know if it really works for most things" rather than highlight the ones with moderate confidence of positive effect this will be less helpful to clinicians as they are more likely to stop paying attention after that first sentence stating the mixed findings and low confidence. I feel the paper needs to be edited throughout with this principle in mind: highlight the positive findings first, followed by the mixed, uncertain, negative findings. This is not just for political reasons BTW but really from my experience as a clinician using this type of document. Line 22. Same comment here—would state the important finding re biofeedback and HA first, then the "overall findings for most conditions were insufficient." P5 line 40. Summary omits positive findings on IBS and hypnosis. P18line 10. As above should state positive findings first in the summary section P21 line 13 As above would switch the order here and state positive conclusions first.especially given the clear statement you are making about biofeedback and HA. Why undermine the potential meaning and impact of the positive finding by prefacing it with the negative findings? Line 33-36. Same comment, would switch the order here. P25 line 19. Seems misleading re IBS findings—which were positive for overall symptoms and GI function although negative for other outcomes. Again leaving that out is confusing and inconsistent with what is stated on line 47 and portrayed in the summary figure on p 27	Thank you. We have edited the document throughout to state the positive findings first in each section, as suggested.
1	line 37: this paragraph omits the fact that hypnosis was found to be effective with moderate confidence for symptom relief and improved GI functioning in IBS (see page 32 line 47). To omit this and then only state that "nor is hypnosis effective for secondary or global outcomes in patients with fibromyalgia or irritable bowel syndrome" This omission is repeated in multiple spots in the paper. Also the summary table in this section is misleading re IBS—and not consistent with table in the detailed section	Thank you. Only findings of positive effect were summarized in the text cited; because there was moderate-confidence evidence of *potential* positive effect for IBS, those results are not represented. The figure showing the summary of findings across all 3 interventions likewise displays only the findings of positive or null effect, and excludes potential positive and unclear effects.
1	Line39. Why include the statement "None of the available evidence…reached a high level of confidence'? Very often guidelines even have no highest level evidence (see ACP guidelines on back pain from last year). I think this statement can prejudice the reader especially readers who do not understand that the level of confidence in the evidence has to do with the quality of the studies to date not with the likelihood of the conclusions being right or wrong.	Thank you. As suggested, we have removed this statement.

1	P19line 10 Would add “With the exception of arthritis/rheumatic diseases” otherwise this is very incongruous when you look at the summary table on the following page where there is a moderate bubble on evidence of positive effect for these conditions.	Thank you. We have made the suggested change to the text.
1	Line51-56. Why are these findings not included in the summary? These conditions are very common and of great relevance to clinicians. You include other low-confidence conclusions in the summary why omit these findings? P 28 line 50. The findings re IBS symptoms and GI function should be included here as well. P 29. Summary figure omits IBS findings, again not consistent with the summary figure in the detailed section on p 27 Line 50. IBS omitted in the conclusions paragraph.	Thank you. The purpose of the summary graph is to show clearly positive or clearly null effects, even if the level of confidence in the evidence was low. We have not included less clear or mixed findings (potential positive or unclear effects). The findings on IBS symptoms and GI function were potential positive effects, and were therefore not included on the summary graph (Figure 6).
1	P 30 Lines 8-14. Question the need to include as this seems editorial and somewhat prejudicial. Des the article cited specifically refer to the issue of non-blinding in CAM studies or in the literature overall? The statement here makes it seem as if this is unique to CAM studies. Also the statement beginning “It is therefore not clear” also seems somewhat prejudicial to me and possibly unnecessary.	Thank you. We have accounted for your feedback by framing this as a debate representing both sides regarding the need for blinding in CAM studies rather than taking a position.
1	Line 43 I do not think it is correct that all of the findings here are not clinically actionable. Biofeedback for HA, guided imagery for RA, etc—particularly given the huge safety margin for these approaches compared to many pharmaceuticals I think they are actionable. If you need to include this statement please clarify with something like “only a few of” or “not all of” these findings. In the clinical standard of care in this area, the safety margin plays a huge role and somewhat counterbalances in many cases the weakness of the published evidence.	Thank you. We have removed the wording that suggests that potential benefits are not clinically actionable.
2	It appears to be that case that the reviewers lacked background knowledge of Biofeedback methods and findings necessary to do the review successfully. If this is true, could reviewers with the necessary background be recruited to start all over and do the review again and separate from Guided Imagery and Hypnosis?	Thank you. We consult technical experts in the framing of our protocol and search strategy. The format of this review as an evidence map requires high-level synthesis of the subject matter, and as such does not reach the level of granularity of a traditional systematic review.
3	2. There is an opportunity to rate the strength of the reviews included. Taking them as equal and at face value misses an opportunity to further comment on confidence. For example, methodological quality may have been rated by those reviews, but was the system for rating quality appropriate? This goes back to the ‘garbage in garbage out’ criticism of reviews in general which could be avoided here and strengthen confidence in overall conclusions.	Thank you. We used the AMSTAR 2007 criteria as a guide and set minimum quality criteria for inclusion. While the AMSTAR 2007 identifies important criteria, there is not one widely agreed upon, validated method for ranking quality beyond that. For example, AMSTAR doesn’t specify which quality assessment methods should be used.
3	3. How many of the separate reviews included the same studies?	Thank you. While we originally included multiple competing reviews, we ultimately chose 1 review to represent each condition/bubble, and examined the overlapping studies when there were multiple reviews

		per condition to make sure there was adequate representation by the selected SR.
3	4. Is there an effect of number of studies or number of reviews on confidence?	Thank you. Not directly, but rather indirectly via sample sizes.
4	At the beginning when you list the TEP, you say I'm from Boston. I was born there but we're based in Cleveland, Ohio.	Pardon our error on your location. That has been corrected.
4	Also, as I was finding articles, I realized that another kind of imagery that fits as a search word here is "Guided Imagery & Music" or GIM (Bonny Method) and it completely escaped me.	Thank you. GIM was capture in our search, and 1 systematic review was found, but did not meet inclusion criteria.
4	Additionally, the term "imagery rescripting" belongs here, particularly for PTSD; and in the treatment of nightmares. Of course, imagery is often a central, 'active ingredient' of a CBT or exposure protocol, but it gets conflated with the other components of treatment, and gets called by another name. So guided imagery doesn't always get its due! :-(Did my best to make up for that here. :-)	Thank you. Imagery rescripting was captured in our search, and 1 meta-analysis was found, but did not meet our inclusion criteria.
5	A weakness of the study, that the authors lightly addressed in the summary section, is the limited list medical conditions evaluated for which the 3 treatment modalities are often applied. For example, biofeedback modalities applied to conditions is variable. For ADHD, there is research using both HRV biofeedback and EEG biofeedback (aka neurofeedback) – both have good support and meta-analysis publications (see Van Doren, et al 2018, European Child & Adolescent Psychiatry). Mention of this omission limitation is suggested. In reference to Table 3, perhaps it could be noted that the absence of a correlation between the treatment modality (GI, Bio, Hyp) and the condition (anxiety, etc) may not reflect absence of evidence because the published studies associated with that condition (e.g., PTSD and biofeedback; PTSD and guided imagery; Insomnia and biofeedback) were not selected or included in the analysis. As this point relates to biofeedback, insertion of this sort of statement might well fit on **page 28 at line 12-13**. An alternative would be to make this "absence of evidence" point in the summary at page 35 line 16 so that it covers all 3 treatment modalities (GI, Bio, Hyp). I see the light coverage of this point on page 35 line 32-33, I just think it is important to make this point strongly as some will review the paper and jump to false conclusions that one of the 3 modalities is not effective for a particular condition.	Thank you. As suggested, we have added a statement at the beginning of the Results section explaining that the list of health conditions in Table 3 and the evidence maps is not exhaustive, and that additional evidence may be available for other health conditions but they did not meet our inclusion criteria. We acknowledge the limitations of evidence mapping, including the potential to miss some good evidence given our reliance on systematic reviews and we have added more language about these limitations to the report and executive summary.
6	1. The authors clearly spent a lot of time and effort on this, but there is a fundamental error that renders the results to have limited usefulness. The authors failed to break down the various forms of biofeedback in the report. There are references to specific forms of biofeedback and the efficacy of same but the conclusions typically only use the term "biofeedback". There are many forms of biofeedback including galvanic skin response, surface electromyography, heart rate variability, temperature and neurofeedback. One cannot only use the term "biofeedback" and that is exactly what the authors have done. For example, one could state "There is evidence for the efficacy of heart rate variability biofeedback in the treatment of generalized anxiety disorder". One should not state "There is evidence for the	Thank you. In Table 4 we list the various forms of biofeedback that were included on the evidence maps, as described by the representative systematic reviews. Because this is an evidence map providing a high-altitude view of the topic, a greater level of detail and granularity is unfortunately not possible. We have added some text to the limitations section addressing this point.

	efficacy of biofeedback in the treatment...". The field of biofeedback is too diverse to not specifically identify the kind (modality) of biofeedback used. Page 21 contains the following paragraph: “Across conditions, the majority of systematic reviews provided insufficient evidence to form conclusions about the effectiveness of different biofeedback modalities on diagnosis-related, secondary, or global outcomes. We found strong evidence that biofeedback is effective for reducing the frequency, duration, and intensity of migraine and tension-type headaches, moderate confidence evidence of benefit on secondary outcomes of headaches such as medication intake, muscle tension, anxiety, and depression, and limited evidence supporting the benefit of biofeedback for self-efficacy.13 We also found strong evidence that biofeedback as an adjunct to PFMT can result in both immediate and long term improvement in urinary incontinence for men after a prostatectomy as compared to PFMT alone, and that the addition of biofeedback had a positive effect on quality of life (moderate confidence).50 There is (moderate confidence) evidence that the addition of biofeedback to usual therapy is more effective for short-term lower limb activity improvement after stroke, such as standing and walking, than usual therapy alone14 and that electrical stimulation with biofeedback is more effective than electrical stimulation alone for fecal incontinence (Figure 4; Table 9 in Appendix D).” What KINDS of biofeedback apply to the above paragraph? If one was interested in gait training for example, what kind of biofeedback has the found potential of positive effect?	
6	2. There are no definitions provided for the kinds of biofeedback used. What is contingent electrical stimulation? Balloon sensory biofeedback? Indirect biofeedback? External laryngeal manometry? and others.	Thank you. We have added definitions to Table 4, as suggested.
6	3. The detailed findings contains the following paragraph: "We also identified limited (low confidence) evidence that biofeedback hemodialysis has the potential to result in lower rates of mortality and intradialytic hypotension (IDH) in patients undergoing hemodialysis experiencing chronic fluid overload or symptomatic IDH.33 Additionally, in patients with fibromyalgia, electromyograph (EMG), but not electroencephalograph (EEG) biofeedback has the potential to improve short and long term pain (but not 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)". This is what the authors should have done throughout the document. As it is we are left with the conclusion on figure 4 which offers no information as to the type of biofeedback that was used for a given disorder.	Thank you. Figure 4 reports the modality as described by the systematic reviews.