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 report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the VA Portland Healthcare System, Portland, OR**,** funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

ACKNOWLEDGMENTS

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

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

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

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

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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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Peer Reviewers

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.

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).

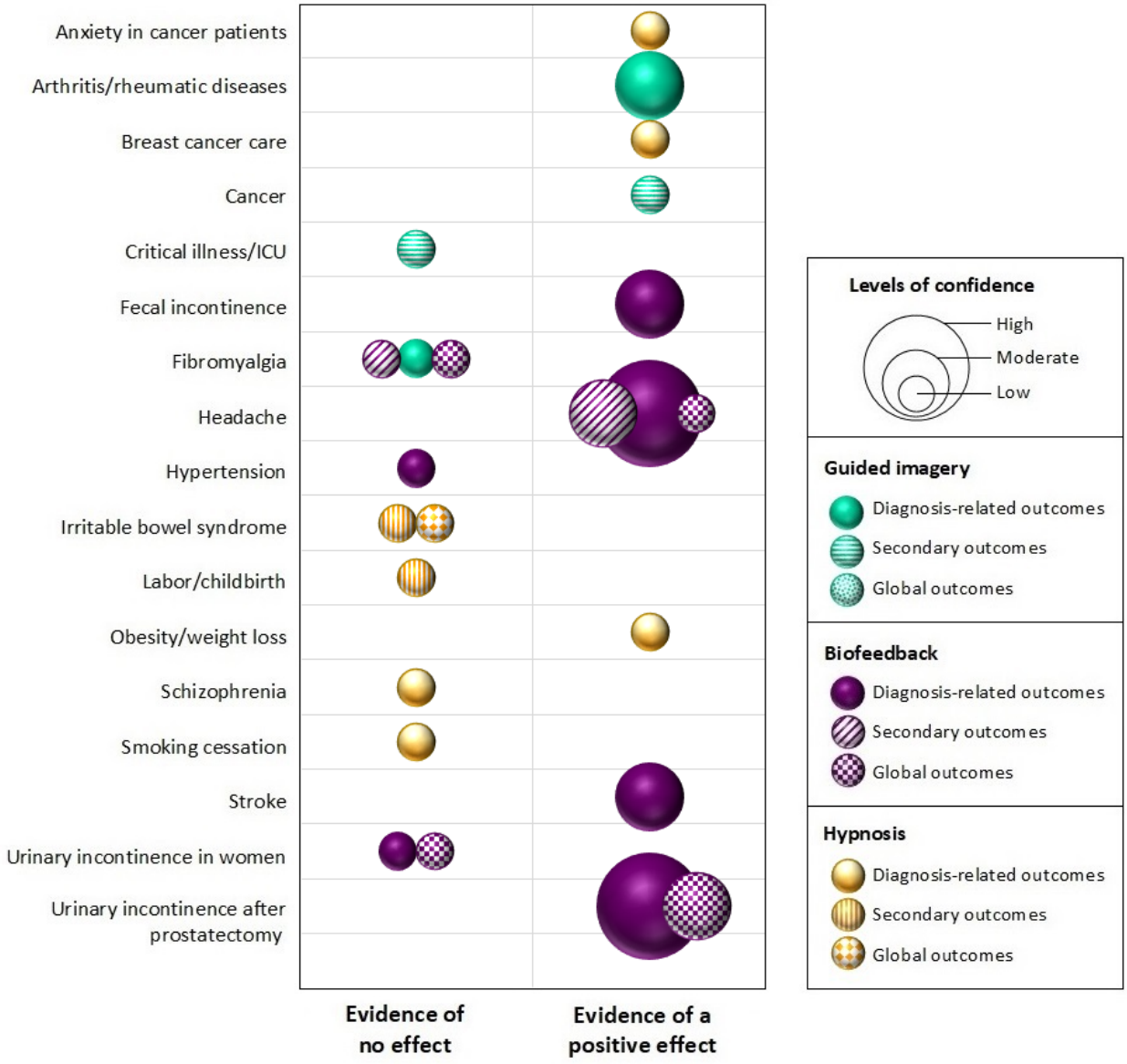
DISCUSSION

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.