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

The authors gratefully acknowledge 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 TEP members; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for report dissemination.

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VHA Coordinating Center for Integrative Health  

Laura Krejci, MSW  
Associate Director  
VHA Office of Patient Centered Care and Cultural Transformation
The authors gratefully acknowledge the following individuals for their contributions to this project:

**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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guy Montgomery, PhD</td>
<td>Associate Professor, Department of Population Health Science and Policy Director, Center for Behavioral Oncology Icahn School of Medicine at Mount Sinai</td>
</tr>
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<td>Clinical Psychologist/Neuropsychologist and Research Health Scientist, Dorn VAHCS Faculty, Departments of Pharmacology, Physiology &amp; Neuroscience, USC School of Medicine</td>
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</tr>
</tbody>
</table>
This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the Portland VA Health Care System in Portland, Oregon, 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 (e.g., 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.
VA Evidence Synthesis Program overview

- Established in 2007
- Provides tailored, timely, and accurate evidence syntheses of VA-relevant, Veteran-focused healthcare topics. These reports help:
  - Develop clinical policies informed by evidence;
  - Implement effective services and support VA clinical practice guidelines and performance measures; and
  - Set the direction for future research to address gaps in clinical knowledge.

- Four ESP Centers across the US:
  - Directors are VA clinicians, recognized leaders in the field of evidence synthesis, and have close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration

- ESP Coordinating Center in Portland:
  - Manages national program operations and interfaces with stakeholders
  - Produces rapid products to inform more urgent policy and program decisions

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

The program solicits nominations for review topics several times a year via the program website.
ESP Center locations

Coordinating Center
Portland, OR

ESP Center
Portland, OR

ESP Center
Minneapolis, MN

HSR&D/QUERI,
VACO
Washington, DC

ESP Center
Los Angeles, CA

ESP Center
Durham, NC
Guided Imagery, Biofeedback, and Hypnosis: A Map of the Evidence

Principal Investigator: Michele Freeman, MPH
Co-Investigators: Chelsea Ayers, BA, Karli Kondo, PhD, MA, Katherine Noonan, PhD, Maya O’Neil, PhD, Benjamin Morasco, PhD, Devan Kansagara, MD, MCR

February 2019

Full-length report available on ESP website: http://www.hsrdr.esrd.research.va.gov/publications/esp/reports.cfm
Poll question

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

- Guided Imagery
- Biofeedback
- Hypnosis
- Not applicable to my role/scope of work
• **Guided imagery** or guided meditation is a therapeutic technique that uses inwardly focused visualization and imaginative content to evoke sensory perceptions for improving mood and/or physical wellbeing; interventions that rely on external sensory input (e.g., virtual reality or mirror therapy) were excluded.

• **Biofeedback** is a method by which a person receives data on physiological measurements (e.g., heart rate, muscle contractions, and brain wave activity) to help regulate physical and mental processes.

• **Hypnosis or hypnotherapy** is the induction of a state of consciousness in which an individual has heightened focus and suggestibility.
Key questions

• Key question 1 – Guided Imagery
  In which populations has guided imagery been examined, and what is the evidence of effectiveness and harms in each of these populations?

• Key question 2 - Biofeedback
  In which populations has biofeedback been examined, and what is the evidence of effectiveness and harms in each of these populations?

• Key question 3 – Hypnosis
  In which populations has hypnosis been examined, and what is the evidence of effectiveness and harms in each of these populations?
Evidence maps

Pros

• Provide a broad (high-altitude) overview of the evidence on an intervention across diverse health conditions/target populations

• Can be useful for finding promising areas for treatment and prioritizing further research

• Based on methods established for systematic reviews (comprehensive literature search, assessment for risk of bias)

Cons

• Based on existing systematic reviews; evidence from recent trials not represented

• Broad brushstrokes about potential benefits; do not characterize magnitude of treatment effects

• Cannot be definitive in determining absence of evidence
# PICOTS – scope parameters

<table>
<thead>
<tr>
<th><strong>Population</strong></th>
<th>Included: Adults (18+) receiving an intervention of interest for any health condition. Excluded: Children and adolescents; healthy/non-elderly volunteers.</th>
</tr>
</thead>
</table>
| **Interventions**                     | • **Guided imagery** – forms include guided meditation, yoga nidra, mental practice, mental rehearsal, Katathym-imaginative Psychotherapy, autogenic training, and integrative restoration.  
• **Biofeedback** – also neurofeedback and neurotherapy.  
• **Hypnosis** – also hypnotherapy. Excluded: GI/B/H as part of a complex or multicomponent intervention |
| **Comparators**                       | Systematic reviews and meta-analyses comparing an intervention of interest to usual care, placebo, or another intervention.                                                                        |
| **Outcomes**                          | • **Primary** effects on diagnosis-related symptoms  
• **Secondary** outcomes, including:  
  - Mental health outcomes (e.g., anxiety and depression) secondary to the diagnosis;  
  - Sleep  
• **Global** outcomes including quality of life, activities of daily living, mobility, social functioning, employment  
• **Harms**                                                                                  |
| **Timing**                            | Any duration of treatment and follow-up.                                                                                                                                                    |
| **Study design**                      | Included: Systematic reviews and meta-analyses that include randomized or non-randomized controlled trials. Excluded: Non-systematic reviews, reviews of reviews, and primary studies. |
Methods – literature search

**Literature search and data sources**

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

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

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

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

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

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

We classified the evidence of effectiveness into 4 categories:

1) **No effect**: a preponderance of null or negative findings.

2) **Unclear**:
   - Mixed findings for a single outcome with no preponderance of either benefit or negative effects, or
   - The number of studies, sample sizes, and/or the methodological quality of the studies were insufficient to form a conclusion about effectiveness.

3) **Potential positive effect**:
   - Mixed findings for a single outcome that include some evidence of benefit, or
   - Multiple outcomes within the same category (primary diagnosis-related/secondary/global) with at least 1 clear finding of benefit.

4) **Positive effect**:
   - Numerous studies with a preponderance of positive findings, or
   - A large, methodologically sound trial showing a positive effect.
# Methods – assessing level of confidence

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

1. **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.
3. **Low**: Small sample size, or major deficiencies in the body of evidence.
4. **Insufficient**: The body of evidence has unacceptable deficiencies.

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

<table>
<thead>
<tr>
<th>Domain: range of points</th>
<th>Description</th>
</tr>
</thead>
</table>
| Sample Size: 1 to 3     | 1: N ≤ 100  
                          2: N = 100-500  
                          3: N = 500+     |
| Consistency: -1 or 0    | 0 = No major flaw,  
                          -1 = Serious inconsistency |
| Directness: -1 to 0     | 0 = No major flaw,  
                          -1 = Limited applicability |
| Overall ROB/study quality: -1 or 0 | 0 = Unclear or low ROB  
                                    -1 = High ROB (poor quality) |
Results – literature flow

2,529 Citations from electronic databases (59.5% from PubMed/Ovid MEDLINE)

4 Citations from other sources (reference lists, key experts)

2,533 Citations compiled for review of titles and abstracts

229 Potentially relevant articles

40 included SRs (2 addressed both KQ1 & KQ3)

12 SRs of guided imagery

16 SRs of biofeedback

14 SRs of hypnosis
Results – N of GIBH trials in targeted health conditions

- Pain, headache: 94
- Hypertension: 35
- Stroke: 17
- Urinary incontinence in women: 32
- Anxiety, cancer: 17
- Anxiety, medical procedures: 17
- Chronic idiopathic constipation: 17
- Fibromyalgia: 14
- Anxiety: 13
- Cancer, breast: 9
- Labor/childbirth: 9
- Urinary incontinence after prostatectomy: 8
- Incontinence: 8
- Fecal incontinence: 7
- Smoking cessation: 7
- Raynaud’s: 7
- Pain, disability-related: 7
- Obesity/weight loss: 7
- Critical illness/ intensive care: 7
- Pain, musculoskeletal: 7
- Irritable bowel syndrome: 7
- Balance/Gait training: 7
- Intradialytic hypotension: 7
- Arthritis/rheumatic disease: 7
- Bruxism, sleep: 6
- Cardiac surgery: 6
- PTSD: 6
- Dysphagia: 5
- Cancer: 5
- Bell’s Palsy: 4
- Schizophrenia: 4
- Menstrual disorders: 4
- Parkinson’s: 3
- Knee osteoarthritis/Gait training: 3
- Depression, postnatal: 1

Biofeedback (16 SRs)
Hypnosis (14 SRs)
Guided Imagery (12 SRs)
### Results – KQ1: Guided Imagery

<table>
<thead>
<tr>
<th>Condition</th>
<th>Evidence of no effect</th>
<th>Unclear/insufficient evidence</th>
<th>Evidence of a potential positive effect</th>
<th>Evidence of a positive effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis/rheumatic disease</td>
<td></td>
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<tr>
<td>Cancer</td>
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<td></td>
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<tr>
<td>Cardiac surgery</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Illness/ICU</td>
<td></td>
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<td></td>
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<tr>
<td>Fibromyalgia</td>
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<tr>
<td>Headache</td>
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<tr>
<td>Insomnia</td>
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<tr>
<td>Menstrual disorders</td>
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<tr>
<td>Musculoskeletal pain</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Parkinson’s</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stroke</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Levels of confidence**
- High
- Moderate
- Low
- Insufficient

*No available evidence on guided imagery reached a high level of confidence.*
Results – KQ1: Guided Imagery

Summary of findings

• 12 SRs examined the effects of guided imagery for anxiety, arthritis, cancer, cardiac surgery, ICU patients, fibromyalgia, headache, menstrual disorders, musculoskeletal pain, Parkinson’s disease, and stroke.

• Pre-recorded scripts on audio or video tapes were most commonly used; in-person sessions were also used in some studies.

• Patients with arthritis/rheumatic diseases experienced positive effects on pain symptoms; level of confidence in the evidence was moderate.

• Possible benefits found in several other populations but the findings were mixed and the level of confidence in the evidence was low overall.

Limitation: variation in what constitutes guided imagery

• Motor imagery (visualizing/imagining movement without performing the movement physically) was excluded in an SR of guided imagery for musculoskeletal pain.

• Mirror therapy and virtual reality interventions – we excluded because they are externally driven processes/externally derived images; SRs in our search yield included these as guided imagery.
Results – KQ2: Biofeedback evidence map

Levels of confidence
- High
- Moderate
- Low
- Insufficient

Outcomes
- Diagnosis-related
- Secondary
- Global

Evidence of no effect | Unclear/insufficient evidence | Evidence of a positive effect | Evidence of a positive effect
---|---|---|---
Balance/gait training | | | |
Bell’s palsy | | | |
Chronic idiopathic constipation | | | |
Dysphagia | | | |
Fecal incontinence | | | |
Fibromyalgia | | | |
Headache | | | |
Hypertension | | | |
Intraventricular hypertension | | | |
Knee osteoarthritis/gait retraining | | | |
Labor/childbirth | | | |
Raynaud’s | | | |
Sleep bruxism | | | |
Stroke | | | |
Urinary incontinence in women | | | |
Urinary incontinence after prostatectomy | | | |
16 SRs of biofeedback used alone or as an adjunct to another therapy

High-confidence evidence of benefit for primary outcomes:
  • Migraine and tension type headache pain
  • Urinary incontinence after prostatectomy, in adjunct with pelvic floor muscle training.

Moderate-confidence evidence of benefit for primary outcomes:
  • Stroke
  • Fecal incontinence

Low-confidence evidence of no effect on primary outcomes:
  • Urinary incontinence in women
  • Hypertension
## Results – Biofeedback techniques used

<table>
<thead>
<tr>
<th>Condition</th>
<th>Biofeedback techniques used</th>
<th>Adjunctive therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance/gait training</td>
<td>Wearable plantar pressure sensors, IMU</td>
<td>---</td>
</tr>
<tr>
<td>Bell’s Palsy</td>
<td>EMG, biofeedback rehabilitation</td>
<td>With mime therapy. Other therapies varied - facial expression exercises, lip movement without eye closure.</td>
</tr>
<tr>
<td>Chronic Idiopathic Constipation</td>
<td>EMG biofeedback, balloon sensory biofeedback, manometry biofeedback</td>
<td>---</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>sEMG, accelerometry, tongue manometry, video endoscopy, respiratory plethysmography, external laryngeal manometry</td>
<td>With swallow therapy</td>
</tr>
<tr>
<td>Fecal Incontinence</td>
<td>EMG biofeedback, balloon sensory biofeedback,</td>
<td>With electrical stimulation</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>EMG biofeedback, EEG feedback, LENS, SMR training</td>
<td>Varied: PMR</td>
</tr>
<tr>
<td>Headache</td>
<td>TEMP biofeedback, TEMP + EMG biofeedback, EMG biofeedback, BVP biofeedback, EEG biofeedback, GSR biofeedback</td>
<td>Varied - relaxation</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Blood pressure biofeedback, indirect biofeedback, direct biofeedback</td>
<td>Varied: relaxation, meditation, imagery, inner quality management</td>
</tr>
<tr>
<td>Intradialytic hypotension</td>
<td>Biofeedback hemodialysis: BVM with dialysate conductivity control, BVM with plasma conductivity-controlled</td>
<td>---</td>
</tr>
<tr>
<td>Knee osteoarthritis/gait retraining</td>
<td>Visual, haptic (not specified)</td>
<td>---</td>
</tr>
<tr>
<td>Labor pain</td>
<td>EMG, skin-conductance biofeedback</td>
<td>Varied - relaxation, PMR, Lamaze,</td>
</tr>
<tr>
<td>Raynaud’s</td>
<td>Thermal biofeedback, thermal feedback + EMG</td>
<td>Varied - autogenic training, relaxation</td>
</tr>
<tr>
<td>Sleep bruxism</td>
<td>Contingent electrical stimulation</td>
<td>---</td>
</tr>
<tr>
<td>Stroke</td>
<td>Weight distribution from a force platform or sensor, muscle activity from EMG, linear gait parameters from foot sensors, joint angle from a goniometer.</td>
<td>With usual therapy including therapist communication</td>
</tr>
<tr>
<td>Urinary incontinence (women)</td>
<td>EMG, vaginal and/or anal squeeze pressure, ultrasound</td>
<td>With pelvic floor muscle training</td>
</tr>
<tr>
<td>Urinary incontinence after prostatectomy</td>
<td>Biofeedback-assisted pelvic floor muscle training</td>
<td>Varied - electrical stimulation</td>
</tr>
</tbody>
</table>
Results – KQ2: Hypnosis evidence map

- Evidence of no effect
- Unclear/insufficient evidence
- Evidence of a potential positive effect
- Evidence of a positive effect

Levels of confidence:
- High*
- Moderate
- Low
- Insufficient

* No available evidence on hypnosis reached a high level of confidence.

Outcomes:
- Diagnosis-related
- Secondary
- Global
14 SRs of hypnosis examined a wide range of clinical conditions.

Low-confidence evidence that hypnosis is effective for:
• Weight loss in obese adults
• Anxiety in patients with cancer
• Symptoms experienced during breast cancer treatment

Low-confidence evidence that hypnosis provides no benefit for:
• Smoking cessation
• Schizophrenia

Factors for low confidence:
• Small samples sizes
• Poor study quality
• Inconsistencies across studies within health condition/target population
Limitations to GIBH evidence maps

- The level of confidence for the majority of outcomes and health conditions was low or insufficient. Few trials/small combined sample sizes and risk of bias in trials were the most common factors.

- There is very little information about the impact of GIBH on quality of life and functional status.

- For biofeedback, we were not able to distinguish the different types of biofeedback modalities and evaluate the utility of specific types of biofeedback.

- The role of blinding
  - The authors of the included SRs often noted lack of patient blinding in trials of GIBH.
  - Blinding is challenging given the nature of these interventions.
  - Expectancy for change may be an integral part of the intervention, in which case blinding would be counterproductive.
Limitations of evidence map approach

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

Primary diagnosis-related outcomes

Evidence of no effect for:

- **Biofeedback**
  - Hypertension
  - Urinary incontinence (women)

- **Guided imagery**
  - Fibromyalgia

- **Hypnosis**
  - Schizophrenia
  - Smoking cessation

Secondary outcomes (eg, depression/anxiety)

Evidence of no effect for:

- **Biofeedback**
  - Fibromyalgia

- **Guided imagery**
  - ICU patients

- **Hypnosis**
  - Irritable bowel syndrome
  - Labor/childbirth

Global outcomes (eg, quality of life, functional status)

Evidence of no effect for:

- **Biofeedback**
  - Fibromyalgia

- **Guided imagery**
  - Urinary incontinence (women)

- **Hypnosis**
  - Fibromyalgia

The level of confidence was low for these findings of no effect.
Conclusions – evidence of positive effects

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

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

- Low-confidence evidence of benefit for **hypnosis** in patients with
  - Obesity
  - Anxiety in patients with cancer
  - Symptoms during breast cancer treatment
The IHCC is charged with developing and implementing CIH strategies in clinical activities, education, and research across the system.

Its **two major functions** are to:
- identify and remove barriers to providing CIH across the VHA system.
- serve as a resource for clinical practices and education for both veterans and clinicians.
CIH Policy Directive

- CIH Directive – SIGNED BY USH 5/19/2017
  http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=5401

  - LIST I: evidence of promising or potential benefit
    - evidence of promising or potential benefit
    - vetted by IHCC Advisory Group
    - VA must provide a mechanism to offer these approaches either within VA facility or in the community

  - LIST II: generally considered safe
    - General recognition of safety requires common knowledge, throughout the expert scientific community (both internal and external to VHA) knowledgeable about the safety of CIH approaches and the impact on Veterans’ physical and mental well-being, that there is a reasonable certainty that the approach is not harmful under the conditions of its intended use.
    - Optional for inclusion in VA facility, depending on capability (staff/space) at sites
CIH Therapies approved to date

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

Chiropractic included already by specific Congressional mandate
Whole Health

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

THE PATHWAY (Empower)
Partners with Veterans to discover their mission, aspiration, and purpose and begins to create an overarching personal health plan

WELL-BEING PROGRAMS (Equip)
Self-Care/Skill Building and Support
Complementary & Integrative Health (CIH)
Health Coaching & Health Partner Support

WHOLE HEALTH CLINICAL CARE (Treat)
Outpatient & Inpatient Health & Disease Management within a Whole Health Paradigm (i.e., Personal Health Planning, CIH, Health Coaching)
If you have further questions, please feel free to contact:

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Benjamin.Kligler@va.gov

Full-length report and cyberseminar available on ESP website:

http://www.hsrdd.research.va.gov/publications/esp/