### **SPECIFIC AIMS**

## <u>Specific Aim 1</u>: To develop an online distance-learning program on the principles of evidence-based practice (EBP) for chiropractic providers.

**Overview:** Evidence indicates that providers of Complementary and Alternative Medicine (CAM) generally demonstrate lower confidence and less favorable attitudes toward research evidence obtained from clinical trials and practice guidelines than their conventional counterparts. This challenge is not confined to one specific geographic region of the US; it exists at the national level. Therefore, potential solutions must include a nationwide approach. One feasible and cost-effective approach might be to provide large numbers of CAM providers with access to online EBP education. However, the effectiveness of a large scale distance learning program has not yet been established for chiropractic clinicians, one of the largest CAM professions.

This study will develop an online EBP educational program by leveraging the faculty expertise, knowledge and resources of the four chiropractic institutions with existing NCCAM R25 educational grants. Northwestern Health Sciences University (NWHSU) is one of these institutions, and has already collaborated with the University of Minnesota to develop a prototype online educational series called "Foundations of Evidence Informed Practice" for CAM providers. As part of the proposed project, we will bring together the four chiropractic R25 grantees to collaboratively refine and enhance NWHSU's "Foundations" series and create new interactive online "booster" sessions specifically for chiropractic practitioners. The program will consist of two parts: 1) ten hours of online foundational EBP training over two months, and 2) four one-monthly online "booster" sessions with interactive case scenarios and an online discussion forum.

## <u>Specific Aim 2</u>: To test the effectiveness of the online distance-learning program on the attitudes, skills, and use of EBP in a sample of chiropractic clinicians.

Overview: We will test the effectiveness of the online EBP training program with an important subset of CAM providers, doctors of chiropractic (DC). The sample will comprise of 250 DCs recruited nationally. DCs will be randomized into two groups; one group will be immediately exposed to the online EBP education intervention and the other group will serve as a wait-list control. The outcome measure will be a validated EBP survey instrument; the Evidence-Based practice Attitude and utilization Survey (EBASE). The EBASE has 3 subscores: 1) Attitude; 2) Skill, and 3) Use. The EBASE will be administered at baseline (0 months) and immediately after completion of the program (6 months). The primary outcome will be the magnitude of change in the EBASE "attitude" sub-score (primary outcome measure) that occurs before/after the educational intervention. Secondary outcome measures include changes in the EBASE "skill" and "use" sub-scores.

We hypothesize that the intervention group will demonstrate a significantly greater change in EBP attitude subscores compared with the wait-list control group at 6 months (<u>between</u>-group comparison). We also postulate that <u>within</u> the intervention group, post-intervention (6 month) EBASE sub-scores will improve from baseline values. The wait-list control group will be exposed to the same educational program at 6 months, and a within-group comparison will be subsequently performed at 12 months (6 months post-intervention).

# <u>Specific Aim 3</u>: To determine the feasibility of expanding the online program to multiple CAM professions and exploring its effectiveness under the R01 mechanism.

Overview: This study will generate important preliminary data and experience to inform the feasibility and design of an R01 application, which will explore the same research question on a larger sample involving a wider range of CAM professions, including acupuncture, Oriental medicine, naturopathy, and massage therapy. The feasibility of the R01 project will be informed by careful tracking of the following: recruitment / participation ratios, adherence rates to the core program and monthly booster sessions, database management issues, computer technology, internet browser issues, and instructional design issues. We will also obtain feedback from participants who complete the program and evaluate their satisfaction with different features of the online educational experience. We will perform an exploratory analysis looking for potential correlations between baseline EBASE scores and demographic variables such as age, gender, previous research experience, and number of years in practice. Our long term goal is to develop and validate an effective online education program in order to raise the EBP literacy of large numbers of CAM providers at the national level.

#### RESEARCH STRATEGY

## 1. SIGNIFICANCE

- 1.1. There is a large gap between the discovery of clinical evidence by researchers and the application of evidence by providers in clinical practice. Despite a surge in the volume and quality of published research evidence and clinical guidelines over the past few decades, this evidence is not being translated into clinical practice<sup>1</sup>. Further, this evidence has only had a limited effect on clinician behavior and ultimately on the treatment provided to patients. This has resulted in a large gap between discoveries of new clinical evidence and clinical practice, which has obvious public health ramifications. One example is the wide variation that exists for the prescription of several common medications such as aspirin and calcium channel blockers, despite clear evidence regarding their best use in clinical practice<sup>2</sup>. Another example is the rate of spine surgery for lumbar disc herniation and spinal stenosis, which have been shown to vary by four-fold among geographic regions in the United States<sup>3</sup>. The Agency for Healthcare Research and Quality has stated that up to two decades may pass before the findings of original research become part of routine clinical practice<sup>4</sup>. Our study is translational in nature and will focus on the dissemination of evidence, which is required before implementation can take place.
- **1.2. There are many barriers to physician adherence to practice guidelines.** A majority of the knowledge translation research to date has focused on physicians and the identification of barriers to the use of evidence-based medical therapies. In an effort to bridge this evidence-practice gap, there have been many investigations into the barriers associated with physician adherence to clinical practice guidelines. A systematic review discovered three broad categories of barriers: physician attitudes, knowledge, and behaviors<sup>5</sup>. *Implementation* barriers related to attitudes include: lack of agreement with guidelines, low perceived self-efficacy of physician, and the challenges of overcoming clinical practice routines and habits. *Implementation* barriers associated with behavior include: inability to reconcile patient preferences with guideline recommendations, presence of contradictory guidelines, lack of time, reimbursement issues, malpractice concerns, and organizational constraints. *Dissemination* barriers are attributed to the large volume of research evidence, the time needed to stay informed, and accessibility of published guidelines.
- **1.3. There are additional barriers to Complementary and Alternative Medicine (CAM) providers' adherence to clinical guidelines**. There is evidence that CAM providers place lower importance on randomized controlled trials and other forms of research evidence in their clinical practices relative to their medical colleagues<sup>6</sup>. There is a lower adherence rate to pediatric vaccination guidelines by naturopathic and chiropractic clinicians as compared to other medical professions<sup>7</sup>. Further, over 50% of chiropractic students who had completed a health promotion and public health course continued to report anti-vaccination attitudes<sup>8</sup>. A large cross-sectional survey of over 1,500 CAM and medical clinicians revealed that less than 25% of acupuncturists and naturopaths rated the results of randomized trials as "very useful", which was far lower than the ratings of internists (58%) and rheumatologists (64%)<sup>9</sup>.

Other barriers to implementation among CAM providers include lack of EBP training and access to research literature. A survey conducted with massage therapists and chiropractors in Canada found both professions reported a lack of critical research appraisal skills and rarely accessed peer-reviewed literature or evidence-based databases<sup>10</sup>. Another study involving qualitative interviews with a small focus group of British chiropractors found six themes that represented typical barriers to EBP uptake, including lack of accessibility to the evidence and poor research appraisal skills<sup>11</sup>.

- **1.4. Dissemination and Implementation (D&I) are two sides of the same coin:** *Dissemination* is the targeted distribution of information to a specific clinical practice audience with the intent to spread knowledge about evidence-based interventions. Dissemination research seeks to uncover the mechanisms by which research evidence is spread through professions and affects changes in provider attitudes and beliefs. *Implementation* is the use of strategies to adopt and integrate evidence-based interventions and change practice patterns within specific settings. Implementation research seeks to understand the behavioral aspects of what affects changes in the actual practice behaviors of healthcare professionals. The barriers to D&I are fairly well known within the context of standard medicine, but are less understood within CAM.
- 1.5. Relevance to the National Center for Complementary and Alternative Medicine (NCCAM):

  The mission of NCCAM is to explore CAM healing practices in the context of rigorous science, to train CAM researchers, and disseminate authoritative information about CAM therapies to the public and professionals. The Third NCCAM Strategic Plan (2011-2015) has three goals¹²; the third of which is to "enable better evidence-based decision making regarding CAM use and its integration into health care and health promotion". Two goals of NCCAM's early history were i) developing foundational scientific evidence for CAM interventions and ii) building multi-disciplinary CAM research capacity where little existed. These goals are gradually being

achieved, yet there still remains a large gap between CAM evidence and CAM practice. This issue is clearly expressed in Strategic Objective 5 of the current NCCAM Strategic Plan: "Develop and Disseminate Objective, Evidence-Based Information on CAM Interventions". Helping the public and health care providers to be better informed about the safety and usefulness (or lack thereof) of CAM interventions, practices, and disciplines is the overarching communication goal of NCCAM. The D&I of evidence-based health information to the public and health care providers is a key component of the mission of NIH.

#### 2. INNOVATION

This study is overtly designed to be an exploratory "high risk-high reward" project. The results will either support or reject our hypothesis that online distance-learning is an effective means by which to positively influence CAM providers' attitudes, skills, and use of EBP on a large scale. We will devote all of our resources to refining, further developing and testing an online distance-learning program based upon the effectiveness of this approach in other health care professions<sup>13</sup> and its potential to be delivered on a national scale to a large number of CAM providers. We believe that exposing chiropractors to a series of customized "CAM and chiropractic-friendly" online educational programs will improve chiropractors' attitudes toward research and EBP, and increase uptake of EBP in clinical practice.

Our study is innovative because we plan to leverage and coordinate the resources of several CAM institutions with existing R25 NCCAM grants along with the EBP outreach efforts of national and state chiropractic organizations. This approach has three basic advantages: 1) we will use existing EBP educational strategies already shown to be effective with students and faculty at these institutions, rather than develop a completely new program; 2) we will spend the majority of research funds on direct participant costs and toward maximizing the sample size; and 3) we will recruit research participants on a national scale at minimal cost by utilizing email addresses from the membership lists of our cooperating chiropractic organizations.

#### 3. APPROACH:

We will test the effectiveness of the distance learning program in a sample of doctors of chiropractic (DCs). The study design will be a prospective randomized wait-list controlled trial with two parallel arms. One group will receive the online EBP education program and the other group will be a wait-list control. The education program will take place over six months and consist of two parts: 1) ten hours of online foundational EBP training over two months, and 2) four once-monthly online "booster" sessions with brief interactive exercises. At six months, the wait-list control group will be given access to the same program.

## 3A. Research Overview

**3A.1. Research Hypothesis:** Our primary hypothesis is that exposure to the online training program will improve the attitudes, self-perceived skills, and use of EBP in clinical practice by CAM providers. If our analysis shows this approach to be effective in this selective sample of DCs, we will design a more definitive R01 proposal for a study with a larger sample size consisting of participants from several CAM disciplines. The long-term implications of this are substantial; online EBP programs could be made accessible to CAM providers nationally and thereby improve the D&I of EBP clinical guidelines on a larger scale across professions.

## 3A.2. Experience of Principal Investigator and Research Team

**3A.2.1. Principal Investigator:** Dr. Schneider has been involved for over 20 years in direct efforts to improve the evidence base of chiropractic practice. He has been a co-investigator on several consensus projects including a role within the Council on Chiropractic Guidelines and Practice Parameters (CCGPP). This resulted in the publication of four best practice guidelines <sup>14,15,16,17</sup> and two systematic reviews <sup>18,19</sup>. In this work with the CCGPP, he coordinated the efforts of multiple co-investigators across different institutions. Dr. Schneider was the first chiropractor to receive a K99/R00 award from NCCAM and has extensive research resources available to him at the University of Pittsburgh, including the Clinical and Translational Science Institute. He has the experience and resources necessary to manage and coordinate the efforts of his co-investigators to successfully implement this R21 study.

**3A.2.2.** Research Team: Dr. Schneider has assembled an international research team that is well qualified to conduct this type of D & I research. At the University of Pittsburgh, he has the support of an experienced biostatistician (Dr. Landsittel), data management personnel, and instructional designers. Dr. Hawk is the current chair of the Scientific Commission of the CCGPP and will have access to contact information for over 10,000 chiropractic clinicians. The CCGPP is ready to promote our study on a national scale, providing a solid foundation for our recruitment strategy. Dr. Leach, the primary author of the EBASE survey, has extensive CAM research experience and has developed a comprehensive EBP educational program for CAM providers. He has written a textbook about clinical reasoning in CAM practice and is considered a leading

expert on improving EBP education within CAM professions. Dr. Evans is the PI of a CAM Research Education Partnership Project (R25 award) in collaboration with the University of Minnesota. She has already developed an online EBP educational series for CAM providers upon which the proposed online EBP program will be based. Refinement and further development of the new EBP program will be done with the assistance of three co-investigators: Dr. Haas, Dr. Long, and Dr. Cramer. They are all PIs of NCCAM R25 educational grants and have extensive experience with the development of EBP training programs at their respective institutions.

### 3B. Preliminary Research

The field of dissemination and implementation research within the area of CAM is relatively new and underdeveloped. Notwithstanding, the PI and co-investigators have been involved in two areas of preliminary work that have been important for setting the stage for the proposed project: 1) Council on Chiropractic Guidelines and Practice Parameters (CCGPP); and 2) NCCAM funded research education projects (R25).

**3B.1. Chiropractic organizations' efforts:** The CCGPP was formed in 1995 through the initiative of the Congress of Chiropractic State Associations (COCSA) and other chiropractic organizations. The mission of the CCGPP is to collect, evaluate, update and disseminate scientific evidence related to chiropractic practice; and to provide practitioners, policy-makers and the public with reliable information on which to base informed health care decisions<sup>20</sup>. To date, the CCGPP has published three guidelines for chiropractic clinicians<sup>21,22,23</sup>. The CCGPP is presently attempting to translate these evidence syntheses into more readily accessible formats for implementation by providers, using a process called DIER (Dissemination, Implementation, Evaluation, and Revision). No data have yet been collected to document the effectiveness of this DIER process in facilitating the dissemination and implementation of chiropractic best practices.

**3B.2. Educational programs (R25 grants):** There are several CAM institutions – including four chiropractic programs - that have received R25 grants from NCCAM within the past five years, with the broad objective of improving the level of EBP literacy among CAM students, faculty, and providers.

Northwestern Health Sciences University (NWHSU) has developed a multifaceted EBP educational program for CAM faculty, students and practitioners of which a key feature is online learning<sup>24</sup>. Developed in collaboration with the University of Minnesota (UM) and in consultation with leading experts on medical information management, Dr. Slawson and Dr. Shaughnessy, the program includes 20 interactive online learning modules in Evidence Informed Practice (EIP). Created by UM instructional designers, health care education specialists, CAM scientists and clinicians, the modules place heavy emphasis on "information mastery". Specifically, the modules promote EBP skills relevant to CAM clinical practice and diminish practitioner burden by focusing on high quality summary sources, such as guidelines and systematic reviews. Three years after initial implementation, 90% of NWHSU faculty have completed the online introductory EIP training. Surveys of these faculty found increased confidence in a range of EBP-related skills and modest changes in EIP behaviors, such as using research to answer clinical questions<sup>25</sup>.

The University of Western States (UWS) in collaboration with the Oregon Health & Science University has taken the approach of broad change throughout the chiropractic curriculum; assessment is general rather than associated with a single class or series. The UWS questionnaire looks at students' EBP knowledge, self-assessed skills, and attitudes upon entering UWS and after their 3<sup>rd</sup> educational year. Compared to a control year, the first two new-curriculum cohorts showed improvement in knowledge (unpublished data). Skills and attitudes were mixed, reflecting both a better understanding of EBP and perception of increased workload. UWS also developed a series of online modules on advanced information literacy and modules on elements of literature critical appraisal. UWS is currently administering an alumni questionnaire on EBP utilization and barriers in practice to determine how well recent chiropractic graduates retain EBP skills and use after graduation.

The National University of Health Sciences (NUHS) has collaborated with the University of Illinois, Chicago to implement a student mentored research program. NUHS has also introduced a sustainable EBP curriculum and shown improvements in the EBP knowledge, attitudes, and skills of its chiropractic students and faculty<sup>26</sup>. The R25 team at NUHS has also produced a 300-page EBP study and practice guide<sup>27</sup> for CAM providers that will be a useful resource for development of the EBP online program and future R01 proposal.

Palmer College of Chiropractic (PCC) has taken the approach of educating its faculty in EBP principles, practice and pedagogy through off-site immersion workshops and on-site training and mentoring in collaboration with The University of Iowa<sup>28</sup>. Faculty incorporated learning outcomes, teaching materials and assessments of EBP knowledge, skills and attitudes into their syllabi, lectures and mentoring of clinical interns<sup>29,30,31</sup>. PCC has assessed student and faculty perceived skills and attitudes through annual surveys and focus groups. Over the 3 cycles of assessments, PCC discovered improved attitudes toward EBP, increased levels of confidence in the use and understanding of EBP, and higher perceived skills related to EBP.

**3B.3. Opportunities for Collaboration**: While progress has been made among the R25 recipients in implementing EBP within the CAM academic programs, they have expressed frustration over the slow progress with their individual attempts at outreach to chiropractic alumni and field clinicians in private practice. Similarly, the chiropractic professional organizations have struggled with creating large scale educational delivery programs to disseminate their evidence-based resources. The proposed project capitalizes on the resources and opportunities that currently exist within the CCGPP, COCSA and the R25 recipients, will create a unique and timely collaboration which, if successful, can be extended to other CAM professions in the future. Key players from CCGPP and COCSA (Schneider, Hawk) - as well as the PIs of the four chiropractic R25 grants - are co-investigators on this project (Haas, Evans, Cramer, Long).

### 3C. Conceptual Framework

This project is built around the 3-part conceptual framework of evidence-based practice, which suggests that good clinical practice should consist of a combination of: 1) the best available evidence; 2) clinician experience; and 3) patient preference<sup>32</sup>. Previous research has shown that passive diffusion of knowledge through peer-reviewed publications is not sufficient to change the practice behavior of physicians<sup>33</sup>. We believe that key barriers to incorporation of the best available evidence in chiropractic and CAM practice are negative attitude and low self-efficacy regarding EBP skills. Self-perceived efficacy refers to the beliefs in one's capabilities to organize and execute the courses of action required to produce specific results<sup>34</sup>. We hypothesize that improving EBP attitudes and self-perceived skills can act as a mediator between publication of research evidence and dissemination of that evidence.

**3C.1. Educational Theories**: Adult learning theory suggests that a practitioner's motivation to learn is self-driven, and dependent on their clinical practice needs<sup>35</sup>. Consequently, EBP learning programs must be designed in a fashion that are relevant to the practitioner-learner. Slawson and Shaughnessy<sup>36</sup> have suggested that the skills of EBP are necessary but not sufficient for the practice of contemporary health care. They have emphasized an "information mastery" approach to knowledge translation, through the "usefulness equation" which encourages clinicians to access pre-filtered and pre-appraised high quality research evidence relevant to their practice. This approach is more intuitive to clinicians and diminishes burden, overcoming some of the traditional barriers to EBP. NWHSU's online EBP series was developed around the information mastery model; we hypothesize this approach will enhance participant motivation to comply with the proposed educational program. Further, we have chosen an online delivery format which, through its asynchronous nature, allows flexibility for the busy practitioner. Well- designed online curricula can be an effective educational strategy for delivering evidence-based materials<sup>37</sup>. Further, after the original cost investment, they only require modest resources in terms of ongoing instruction and assessment.

3C.2. Primary Outcome Measure: We will utilize the Evidence-Based Practice Attitude and Utilization

Survey (EBASE) to measure CAM provider attitude, skill and use of EBP. This instrument has demonstrated good internal consistency, content validity, and acceptable testretest reliability<sup>38</sup>. EBASE contains 84 items divided into seven parts, with each section addressing a different construct using Likert scales. Of interest to this study are:

1) Part A: 9 item sub-score about Attitudes toward EBP;
2) Part B: 13 item sub-score about Self-perceived EBP Skills; and 3) Part D: 8 item sub-score about Use of EBP resources in clinical practice. Normative data for the sub-scores are available<sup>39</sup> and the developer of the EBASE instrument - Dr. Matthew Leach – is a co-investigator on this study.

#### Table 1: NWHSU "Foundations of EIP"

#### Course 1: Overview of Evidence Informed Practice (EIP):

Evidence Informed Practice, Introduction to Research Evidence, Clinical Experience, Patient Presentation

#### Course 2: Types of Research:

Basic Science, Clinical Research, Randomized Clinical Trials, Quantitative and Qualitative Research, Observational Research, Summary Research

#### Course 3: Understanding Research:

Validity and Study Quality, Basic Statistics, Numbers Needed to Treat, Evidence Pyramid and Evidence House

## Course 4: Using Evidence in Practice:

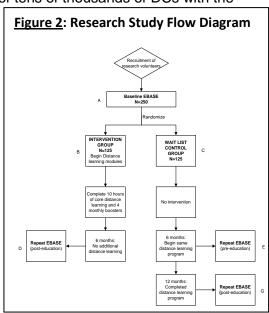
Information Mastery, Finding Research, Assessing Articles About Treatment, Assessing Summary Research, Assessing Experts

**3C.3.** Primary Intervention: Online Distance EBP Education: The proposed EBP educational program will consist of two parts: 1) ten hours of online foundational EBP training over 2 months, and 2) four one-monthly online "booster" sessions with interactive case scenarios and an online discussion forum. Part I of the online EBP intervention will be based upon the NWHSU "Foundations of EIP" program (Table 1). This will be asynchronous, and instructor independent; participating practitioners will complete the courses on their own time within two months of enrolment. Part II of the EBP online program will consist of "booster" sessions, which take place in months 3 to 6. These sessions will serve to reinforce the principles introduced in the initial training though the application of EBP and EBP resources (e.g. critical appraisal tools). Each month, e-mail alerts will be sent to participating practitioners, with a link to an online interactive case scenario relevant to chiropractic practice. Completion of the scenarios will again be asynchronous. Participants also will be encouraged to

participate in a simultaneous online discussion forum moderated by the project PI and co-investigators. The online discussion will focus on key aspects of the case scenario. It will also encourage participants to discuss similar real-world issues occurring in their own practices, which may allow them to further appreciate EBP and incorporate it into their clinical work<sup>31</sup>. By inviting participants' own clinical experiences into the discussion, we hope to facilitate important changes in EBP attitudes, skills and use<sup>40</sup>.

## 3C. Specific Aims

- <u>3C.1. Specific Aim 1</u>: To develop an online distance-learning program on the principles of evidence based practice (EBP) for chiropractic providers.
- **3C.1.1. Overview:** The key purpose of this Aim is to leverage the expertise of the R25 faculty by fostering a collaborative effort to refine and develop an online education program, consistent with the basic learning topics listed in Table 1. We will use the ADDIE instructional model, which provides an iterative framework for analysis, design, development, implementation and evaluation of our online educational strategies<sup>41</sup>. Our approach will continue to emphasize interactive practice exercises and repetition, which enhance effectiveness<sup>42</sup>. The development plan focuses on the two parts of the proposed EBP educational program: 1) ten hours of online foundational EBP training over two months, and 2) four one-monthly online "booster" sessions with interactive case scenarios and an online discussion forum.
- **3C.1.2. Development Plan Part I:** With the consultation of an instructional designer, we will conduct an analysis of NWHSU's "Foundations of EIP" program, which will serve as the foundation for the experimental intervention in our study. The R25 Pls will provide suggestions and oversight for modifications to specifically meet the needs of chiropractic practitioners; it is anticipated that only slight changes will be needed to meet the project's goals. The final product will be a 10-hour online program divided into twenty 30-minute modules. The modules will be designed as "reusable learning objects", which are flexible and easily modified to accommodate new content, including interactions, examples, and learner-assessments of EBP knowledge.
- **3C.1.3. Development Plan Part II:** Four one-monthly "booster" sessions will be created to supplement Part I of the online program, for repeated exposure and practice. The "booster" sessions will consist of interactive case scenarios and an online discussion forum related to the scenario, which will provide a virtual "learning community" for participants. The interactive case scenarios will be designed and developed by the R25 Pls, in collaboration with the instructional designer, using the same online delivery platform as the online modules. The R25 Pls and proposed project investigators will serve as facilitators of the online discussion forums; they will receive training in online discussion facilitation by the instructional designer and Dr. Evans.
- <u>3C.2. Specific Aim 2</u>: To test the effectiveness of the online distance-learning program on the attitudes, skills, and use of EBP in a sample of chiropractic clinicians.
- **3C.2.1. Recruitment Strategy**: We will recruit 500 DCs to take an online version of the EBASE. Research subjects will be recruited utilizing the membership resources of the CCGPP and COCSA. Dr. Hawk (Co-I) is the current CCGPP Commission Chair and will facilitate these recruitment efforts. The CCGPP and COCSA both support this application and will provide email forwarding access to their membership databases (see letters of support). This will allow us to recruit from a potential pool of tens of thousands of DCs with the
- support of these two large national chiropractic organizations; greatly enhancing our recruitment efforts. We will also run print display advertisements in several national chiropractic journals. We will offer research participants free continuing education credits for completion of the online educational program, and a \$25 payment for completing each of the EBASE surveys (baseline and post-intervention).
- **3C.2. Randomization:** We will randomly select a sample of 250 subjects from the larger pool of 500 survey participants. Sample size is limited to 250 due to budget constraints. Stratified randomization will be used to balance the two intervention groups by quartile of baseline EBASE scores.
- **3C.2.3. Research Study Flow**: We will administer the EBASE instrument to our sample to measure their baseline subscores on Attitude, Skill, and Use of EBP. We will randomize 125 subjects to the intervention group (the online EBP educational program) and the remaining 125 to a wait-list control group (Figure 2). EBASE will be administered again to both groups at



six months. We will perform both within-group (B vs D;C vs E) and between-group (D vs E) comparisons of the changes in EBASE sub-scores from baseline to six months. At 6 months, the wait-list control group will be offered the same online education intervention and will be administered EBASE (G) again at 12 months (6 months post-education). A within-group comparison will be made between the control groups' pre and post intervention scores (C vs G).

**3C.2.4. Statistical Analysis**: The primary analysis will use a regression model to compare the intervention and control groups in the 6-month change (from baseline) in the "Attitude" sub-score of the EBASE instrument, adjusting for differences in the baseline attitude sub-score. Additional covariates will be added to the model including any confounders (changing the intervention coefficient by more than 10%) or covariates that add significantly to the model. Alpha will be set at .05. Even with some skewness, the sample size per group (of 125) will likely be sufficient for normality assumptions as long as the data are not extremely skewed or non-normal; otherwise transformations will be explored to conduct the regression models. The analysis will be repeated on secondary variables, the skill and use sub-scores of EBASE.

We will perform within-groups analysis to compare baseline to 6-month post-intervention scores in both arms of the study. We will also describe associations between baseline demographic variables/participant characteristics and baseline EBASE scores using univariate and multiple regression analysis.

- **3C.2.5. Power Analysis**: For simplicity, the power for Specific Aim 1 is based on the 2-sample t-test for differences in the change score for the EBASE Attitude sub-score. The actual covariate-adjusted analysis will be somewhat more powerful. We do not have preliminary data on EBASE change scores, however we can justify this outcome using an effect size calculation. A sample size of N=125 yields 88% and 98% power for relatively small effect sizes of 0.4 and 0.5, respectively. Alternatively, if we assume equal baseline distributions given the randomized design, we can evaluate the power for clinically meaningful differences in scores based on our preliminary data. More specifically, for the Attitude sub-score, the standard deviation from past studies was 4.9 with a mean of 27.4<sup>34</sup>. A clinically meaningful difference of a 20% change would therefore correspond to a change of 5.5 (i.e. overall a 1-standard deviation difference), for which we have over 99% power to detect.
- <u>3C.3. Specific Aim 3</u>: To determine the feasibility of expanding the online program to multiple CAM professions and exploring its effectiveness under the R01 mechanism.
- **3C.3.1. Analysis:** We plan to generate descriptive statistics regarding adherence rates to the basic online program and the four additional monthly interactive exercises, response rates to the recruitment strategies, telephone screening ratios, and drop-out rates. We will also collect data related to participant satisfaction and preferences related to the educational delivery methods via online surveys at the completion of Part I and again at the completion of Part II of the online program. These data will be used descriptively and provide important information regarding the feasibility of delivering an online EBP program for other CAM professions, as well as potential ideas for program optimization.
- **3C.3.2. R01 Development Plan:** Upon completion of the R21 specific aims, we will use the data collected in this project to inform the design, development and implementation of a similar EBP project for other CAM practitioners, including naturopaths, massage therapists, acupuncturists and Oriental medicine providers. The research team will collaborate to further refine and optimize the online educational program to achieve positive changes in EBP attitudes, skills and behaviors in these other CAM practitioners.

## 3D. Limitations and Solutions:

- **3D.1.** Recruitment: Response rates for standard survey research of CAM providers vary greatly, ranging between 33% and 77%<sup>43,44</sup>. However, we do not have previous data regarding response rates to a request for participation in online education programs. We have enlisted the cooperation of the CCGPP and COCSA for recruitment. These organizations estimate the total size of their membership pool to be approximately 10,000. We only require a response rate of 5% to achieve the recruitment goal of 500 survey participants, and a 2.5% response rate for the educational program. We are confident in our ability to recruit these samples due to the strong commitment by these large national chiropractic organizations to this study.
- **3D.2.** <u>Lack of implementation research</u>: This study will be limited to exploring the effect of the online education intervention on the *dissemination* of EBP knowledge and skill to a sample of chiropractors, and will not provide any data about *implementation* within chiropractic clinics. Within the time constraints and limited budget of the R21 grant mechanism, it would be overly ambitious to make any serious attempt to assess the implementation of EBP in chiropractic practice. The results of this study will inform the design of a larger R01 project that will have the necessary budget, time, and resources required to tackle both components.
- **3D.3.** <u>Generalizability:</u> While our study results may not be generalizable to all CAM professions, we feel the experiences gained during this study will provide valuable information for the research team to modify and refine the EBP education program for a wider audience of CAM providers under the R01 mechanism.

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