



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Centers for Disease Control and Prevention

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National Center for Health Statistics  
3311 Toledo Road  
Hyattsville, Maryland 20782

September 29, 2020

Margo Schwab, Ph.D.  
Office of Management and Budget  
725 17th Street, N.W.  
Washington, DC 20503

Dear Dr. Schwab:

The staff of the NCHS Collaborating Center for Questionnaire Design and Evaluation Research (CCQDER) (OMB No. 0920-0222, Exp. Date 08/31/2021) plans to conduct a cognitive interviewing study to examine questions on complementary health approaches and well-being for the National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2020).

We propose to start recruiting for volunteer participants as soon as we receive clearance and to begin interviews as soon as possible after that.

#### Cognitive Interviewing Methodology

The methodological design of this proposed study is consistent with the design of most NCHS/CCQDER cognitive interviewing studies: the purpose is to identify the various patterns of interpretation that respondents consider when formulating an answer to a survey question as well as any problems experienced. Findings reveal the construct captured by each question, patterns of interpretation across respondent groups, and potential sources of response error. This project will contain iterative rounds of cognitive testing (not to exceed the requested burden detailed in the burden table on page 6 of this letter) to allow questions to be revised and re-tested; thus, creating a full set of validated questions. Interviews are in-depth and semi-structured; analysis is conducted using qualitative methodologies. Findings from all CCQDER studies are documented in a final report and made publicly accessible on a searchable website at <https://wwwn.cdc.gov/QBank>.

Proposed project: Cognitive testing of questions on complementary health approaches and well-being

Overview of procedure for cognitive testing

This cognitive interviewing study will evaluate a series of proposed questions for the National Health Interview Survey (NHIS) which is slated to be fielded in 2022. The instrument consists of 10 questions. The first 9 questions focus on complementary and alternative health approaches while the 10<sup>th</sup> focuses on general well-being.

*Background Complementary Health Approaches:* The mission of the National Center for Complementary and Alternative Health (NCCIH) is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care. The purpose of the set of questions for the National Health Interview Survey (NHIS) is to expand knowledge of complementary health approaches. NCCIH aims to answer the following questions: Who uses complementary health approaches and why? Are there significant differences in use by racial or ethnic groups? Do factors such as age, gender, income, or health status influence the use of complementary health approaches? The set of questions on the prevalence of selected complementary health approaches have provided the most current and comprehensive picture of Americans' use of complementary health approaches every 5 years. Scientific evidence informs decision-making by the public, by health care professionals, and by health policymakers regarding use and integration of complementary health approaches. NCCIH uses these data to monitor safety and effectiveness of these therapies.

The rationale and origin for each of the questions in the Complementary Health Approaches Supplement are described below:

**Question 1:** This question was on the NHIS core for decades.

**Questions 1-9 a:** These questions have not been tested before as worded, but in 2007 and 2012 data were collected on the specific health condition for which respondents used complementary health approaches, including many pain conditions.

**Questions 1-9b:** In 2007 NHIS included a question about using complementary therapies for “general wellness or disease prevention.” This was cognitively tested at NCHS.

**Questions 1-9c:** These questions have not been tested and represent a new concept (getting back to original good health rather than a band-aid approach to keep health from deteriorating).

Rationale for including the 3 follow-up questions: The use of complementary health approaches to promote wellness is a research focus area for NCCIH. Some people use complementary health approaches in an effort to promote general well-being or wellness, rather than to help manage symptoms of a health problem. Research sponsored by NCCIH suggests that people who use complementary approaches for wellness tend to have better overall health, higher rates of physical activity, and lower rates of obesity than those who use complementary approaches to

help manage a health problem. Previous surveys show that when individuals do use complementary health approaches for a specific health condition (vs. wellness) the most common reason is to treat or manage pain. More research is needed to better understand how certain complementary health approaches may be useful in improving a personal sense of well-being.

**Questions 2-3:** NHIS asked about these topics in 2002, 2007, and 2012 and the questions were tested in the NCHS cognitive lab.

**Questions 4, 7 and 9:** These topics were on the 2002, 2007, 2012, and 2017 surveys. All except 2017 were tested in the NCHS cognitive lab.

**Questions 5 and 6:** These are new items, not fielded before. NCCIH would like to find the prevalence of using music and therapy since there are no national data on this and they fall within the mission of NCCIH.

**Question 8:** This topic was asked on the 2012 and 2017 NHIS surveys. The 2012 survey was tested in the NCHS cognitive lab.

*Background well-being:* In order to select a single question to measure life satisfaction for inclusion on the NHIS, two existing measures of well-being will be tested. Both the 11-point SWL measure and The Cantril Self-Anchoring Striving Scale have previously been used on the Gallup World Poll.

The Complementary Health Approaches and well-being questions we are evaluating are included as Attachment 1. The testing procedure conforms to the cognitive interviewing techniques that have been described in CCQDER's generic OMB clearance package (OMB No. 0920-0222, Exp. Date 08/31/2021).

#### Cognitive Interview Procedure

Procedures for the cognitive interviews will follow what has been approved in CCQDER's generic clearance (0920-0222, current expiration: 8/31/2021). In short, potential respondents will be recruited using advertisements in media, via word of mouth or from CCQDER's respondent database. Potential respondents will be screened by CCQDER recruiters in order to construct a suitable purposive sample. Interviews will be conducted either face-to-face or via video conference, depending on the social situation and CCQDER's policies and abilities. Interviews will be video recorded, and these recordings and the interviewers' notes will be used in CCQDER's Q-Notes software to conduct analysis.

Recruitment We propose to recruit 40 English speaking adults (aged 18 and over) who may use some form of complementary or alternative health approaches. Recruitment of individuals will be guided first by their experience with complementary or alternative health approaches. Secondly, we aim to recruit respondents with a roughly even mix of age, race, and educational attainment. The initial goal is to recruit groups in equal proportion, to the extent possible – that is, within the constraints of those willing to participate in the study. However, because qualitative sampling is based on theoretical relevance more than equal cell sizes, on-going

analysis may reveal the need to recruit more from one group than others. As noted above, respondents will be recruited using advertisements in media, via word of mouth or from CCQDER's respondent database (the advertisement to be used in this effort is available as Attachment 2).

Screening and scheduling procedure The first contact with potential respondents will occur in response to the flyers or advertisements. Interested persons will leave contact information (name and telephone number) on the CCQDER voice mail system or in an email. A CCQDER Recruiter will then call the potential respondent and give a brief description of the nature of the study, video conference and recording procedures, and monetary incentive. The CCQDER Recruiter will determine through a brief series of questions whether the potential respondent possesses the desired research characteristics (e.g., we ask for gender and age to avoid interviewing people with very similar demographic characteristics). The 5-minute screener used to determine eligibility of individuals responding to the newspaper advertisements/flyers is shown in Attachment 3a. The 5-minute screener used to determine eligibility of individuals from the CCQDER Respondent Database is shown in Attachment 3b. Note that wording of the templates have been approved and are contained within our umbrella package. Only project specific information has been added to the documents. It is anticipated that as many as 60 individuals may need to be screened in order to recruit 40 participants.

If the person does possess the desired research characteristics and would like to participate, he/she will be scheduled for an interview. Otherwise, the volunteer will be asked whether he/she would be interested in participating in future laboratory interviews. Telephone numbers and the minimal demographic information listed earlier will be obtained for all scheduled volunteers and for those who would like to be contacted in the future. For those callers who are ineligible for the study and do not want to be contacted in the future, only demographic characteristics will be maintained for future analysis of successful recruitment efforts.

Interview Methodology Cognitive interviews for the Complementary Health Approaches project will be one-on-one between a single interviewer and a respondent and will be 60 minutes long at most. Interviews will be conducted by CCQDER staff as well as Strategic Innovative Solutions (SIS) contractors. SIS contractors have undergone confidentiality training as well as extensive training by CCQDER staff in CCQDER methods and procedures. Given the social distancing requirements of the COVID-19, interviews will most likely take place via video conference through Skype or Zoom. These platforms have been approved by CDC and NCHS Information Security Offices.

All interviews, including those conducted via video conference and those conducted in-person will be video and audio recorded to allow researchers to review the behaviors and body language of the respondents. These recordings will also allow researchers to ensure the quality of their interview notes. Recordings will be used in accordance with the CCQDER Data Storage and Access Policy. Researchers from CCQDER, SIS contractors and the Division of Health Interview Statistics (DHIS), who are working on the project, will use the recordings for research purposes. Recordings will remain under CCQDER staff control.

For in-person interviews, after respondents have been briefed on the purpose of the study and procedures that CCQDER routinely takes to protect human subjects, respondents will be asked to read and sign an Informed Consent document (Attachment 4a). Respondents will also be asked to fill in their demographic characteristics on the Respondent Data Collection Sheet (Attachment 5a).

For virtual interviews, a member of the CCQDER Operations Team will begin each interview with introduction text explaining the general purpose of the survey, providing the confidentiality and Paperwork Reduction Act language, and informing the respondent that their participation is voluntary and that they may refuse to answer any question (Attachment 4b). Only project specific information has been added to the document. The Operations Team member will collect basic demographic information via the Respondent Information Sheet (Attachments 5b). This document is contained in our umbrella package. Finally, the operations team member will inform the respondent about the need to video record the interview.

At this point, the interviewer will join the video conference and brief the respondent on the purpose of the study and the procedures that CCQDER routinely takes to protect human subjects. The respondent will be asked to vocally affirm their consent to being interviewed. Because many interviews will not take place in person, and it will not be possible for respondents to read and sign the usual informed consent document, a waiver of signed informed consent has been requested from NCHS' ERB. If a respondent does not end the call, consent will be assumed. In the rare instance that consent to record the interview is not granted, the session will not be recorded. In this case the interviewer will depend on their handwritten notes when conducting analysis. If the respondent grants consent to record the interview but changes his/her mind while the session is being recorded, the interviewer will ask for verbal consent to retain the interviewing materials and the portion already recorded. The interviewer will get verbal consent from the respondent to do so prior to turning off the recording software. If the respondent does not give consent for the CCQDER to retain the recording it will be deleted from all locations. Once deleted, the file is no longer available for use. A note will be placed in the hardcopy file and the CCQDER database indicating that particular recording (identified by the unique identification number assigned to the respondent) has been destroyed.

NCHS government issued encrypted laptops will be used to video and audio record the interviews conducted virtually. CCQDER staff and SIS contractors will also use the NCHS government issued encrypted laptops to input their interviewer notes into Q-Notes. Within 24 hours, a CCQDER staff member will review the interview notes and will delete any direct or indirect personal identifiable information (PII) if found.

Extreme care will be taken with all recordings from the interviews conducted virtually. Once the video and audio recordings are transferred to the QDRL Network, the recordings will be deleted from interviewers' devices. Once deleted, the files are no longer available for use.

Interviews will be conducted using concurrent probing, whereby respondents are presented survey questions and asked to explain how and why they answered as they did. The interviewer will use probes extensively to ascertain the degree of comprehension and the recall processes involved. The interviewer may also ask the respondent to think aloud while answering.

After in-person interviews, respondents will be given the thank-you letter signed by the Director of NCHS (Attachment 6), a copy of the informed consent document, and \$40.

Within 7 business days of the conclusion of virtual interviews, the respondent will receive their monetary incentive via FedEx mail along with a thank you letter (Attachment 6), information explaining the terms of consent and contact information for the CCQDER Laboratory Manager, the NCHS ERB Chair, and the NCHS Confidentiality Officer.

We propose giving participants \$40 incentives, which is our standard incentive. In total, for this project, the maximum respondent burden will be 55 hours. A burden table for this project is shown below:

<b>Form Name</b>	<b>Number of Participants</b>	<b>Number of Responses/ Participant</b>	<b>Average hours per response</b>	<b>Response Burden (in hours)</b>
Screener (recruited from newspaper/flyer)	40	1	15/60	10
Screener (recruited from respondent database)	20	1	10/60	4
Questionnaire	40	1	55/60	37
Respondent Data Collection Sheet (NCHS interviews or offsite)	30	1	5/60	3
Respondent Data Collection Sheet (virtual interviews)	10	1	5/60	1
<b>Total</b>				<b>55</b>

Attachments (6)

cc:

S. King

J. Zirger

DHHS RCO