 **1. Study Identification**

* **Unique Protocol Identification Number** **\***  
  NA

**Brief Title** **\***  
A randomized trial of internet-based decision aid for perimenopausal and menopausal women

**Acronym** **[\*]**  
NA

**Official Title** **\*§**  
Definition: The title of the clinical study, corresponding to the title of the protocol.

**Study Type** **\***  
Definition: The nature of the investigation or investigational use for which clinical study information is being submitted. Select one.

* + Interventional (clinical trial): Participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes.

 **2. Study Status**

* **Record Verification Date** **\***  
  Definition: The date on which the responsible party last verified the clinical study information in the entire ClinicalTrials.gov record for the clinical study, even if no additional or updated information is being submitted.

**Overall Recruitment Status** **\***  
Definition: The recruitment status for the clinical study as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical study has an Individual Site Status of "Recruiting," then the Overall Recruitment Status for the study must be "Recruiting." Select one.

* + Recruiting: Participants are currently being recruited, whether or not any participants have yet been enrolled

**Why Study Stopped** **\*§**  
Limit: 250 characters.  
Definition: NA – the study is ongoing).

**Study Start Date** **\*§**  
12 Jan 2022

**Primary Completion Date** **\* 2/15/2022**

15 Feb 2022

**Study Completion Date** **\*§**

15 Feb 2022

 **3. Sponsor/Collaborators**

**Responsible Party, by Official Title** **\***  
Definition: An indication of whether the responsible party is the sponsor, the sponsor-investigator, or a principal investigator designated by the sponsor to be the responsible party. Select one.

* Principal Investigator: The individual designated as responsible party by the sponsor (see Note)

**Investigator Information**  
If the Responsible Party, by Official Title is either "Principal Investigator" or "Sponsor-Investigator," the following is required:

**Investigator Name**: Andrea Z. LaCroix

* **Investigator Official Title**: Professor and Chief of Epidemiology, Family Medicine and Public Health
* **Investigator Affiliation**: University of California San Diego

**Investigator Name**: Katherine A. Guthrie

* **Investigator Official Title**: Professor, Cancer Prevention Program Public Health Sciences Division, Fred Hutch
* **Investigator Affiliation**: Fred Hutchinson Cancer Research Center

**Investigator Name**: Susan D. Reed

* **Investigator Official Title**: Professor, Obstetrics and Gynecology
* **­Investigator Affiliation** University of Washington

**Name of the Sponsor** **\***  
National Institute of Health - National Institute on Aging

**Collaborators**  
Definition: Other organizations (if any) providing support. Support may include funding, design, implementation, data analysis or reporting. The responsible party is responsible for confirming all collaborators before listing them.  
Limit: 160 characters.

 **4. Oversight**

**Human Subjects Review** **\***  
Definition: Studies must have approval (or be exempt, as appropriate) from a Human Subjects Protection Review Board prior to the enrollment of the first participant to be eligible for registration. A study may be submitted for registration prior to approval by the review board so long as the study is not yet recruiting participants.

* + **Human Subjects Protection Review Board Status** **\***  
    Definition: Indicate whether a clinical study has been reviewed and approved by at least one human subjects protection review board or such review is not required per applicable law (for example, 21 CFR Part 56, 45 CFR Part 46, or other applicable regulation). Select one.
    - Submitted, approved: Review board approval has been requested and obtained
    - **Board Approval Number** **[\*]**  
      Definition: Number assigned by the human subjects review board upon approval of the protocol. May be omitted if status is anything other than approved. (*Will not be made public - for administrative purposes only.*)
    - **Board Name** **[\*]**  
      Definition: Full name of the approving human subjects review board. (*Will not be made public - for administrative purposes only.*)
    - **Board Affiliation** **[\*]**  
      Definition: Official name of organizational affiliation of the approving human subjects review board. (*Will not be made public - for administrative purposes only.*)  
      Limit: 255 characters.
    - **Board Contact** **[\*]**  
      Definition: Contact information for the human subjects review board. (*Will not be made public - for administrative purposes only.*)
      * **Phone** (or Email required): Phone number
      * **Extension**: Phone extension, if needed
      * **Email** (or Phone required): Electronic mail address.
      * **Address**: Mailing address for the board, including street address, city, State or province, postal code, and country.
* **Data Monitoring Committee NONE**

 **5. Study Description**

* **Brief Summary** **\***  
  Definition: A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public.  
  Limit: 5000 characters.

 **6. Conditions and Keywords**

**Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study** **perimenopause, menopause**

<https://id.nlm.nih.gov/mesh/D008593.html>

* **term** (MeSH Term) T025553
* **preferredTerm** (MeSH Term) T025552
* **scopeNote** "The last menstrual period. Permanent cessation of menses (MENSTRUATION) is usually defined after 6 to 12 months of AMENORRHEA in a woman over 45 years of age. In the United States, menopause generally occurs in women between 48 and 55 years of age."
* **identifier** "M0013380"
* **MeSH Heading**
* Perimenopause
* **Tree Number(s)**
* G08.686.157.500.562
* G08.686.841.249.500.562
* **Unique ID**
* D047648
* **RDF Unique Identifier**
* [http://id.nlm.nih.gov/mesh/D047648](https://id.nlm.nih.gov/mesh/D047648.html)
* **Scope Note**
* The transitional period before and after [MENOPAUSE](https://meshb.nlm.nih.gov/record/ui?ui=D008593). Perimenopausal symptoms are associated with irregular [MENSTRUAL CYCLE](https://meshb.nlm.nih.gov/record/ui?ui=D008597) and widely fluctuated hormone levels. They may appear 6 years before menopause and subside 2 to 5 years after menopause.

**Keywords**  
Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH)-controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

[PREMENOPAUSE](https://meshb.nlm.nih.gov/record/ui?ui=D017697); and [POSTMENOPAUSE](https://meshb.nlm.nih.gov/record/ui?ui=D017698)

Hot flashes, internet-based intervention

**7. Study Design**

* **Interventional Study Design** **\*** (*For interventional studies only*)  
  Definition: A description of the manner in which the clinical trial will be conducted, including the following information:
  + **Primary Purpose** **\*§**  
    Definition: The main objective of the intervention(s) being evaluated by the clinical trial. Select one.
    - Health Services Research: One or more interventions for evaluating the delivery, processes, management, organization, or financing of healthcare
    - If description is asked: Primary purpose of this RCT is to evaluate the utility of an internet-based decision tool for menopause treatment and management
  + **Study Phase** **\***  
    Definition: For a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21 and in 21 CFR 312.85 for phase 4 studies. Select only one.
    - N/A: Trials without phases (for example, studies of devices or behavioral interventions).
  + **Interventional Study Model** **\*§**  
    Definition: The strategy for assigning interventions to participants.
    - Parallel: Participants are assigned to one of two or more groups in parallel for the duration of the study
    - **Model Description**  
      Definition: Provide details about the Interventional Study Model.  
      Limit: 1000 characters.
  + **Number of Arms** **\*2§**  
    Definition: The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during all periods or phases.

Note: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

* + **Masking** **\*§**  
    Definition: The party or parties involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual participants. Select all that apply.
    - Roles, if Masking:
      * Participant

**Masking Description**  
Definition: Provide information about other parties who may be masked in the clinical trial, if any.  
Participants were randomly assigned to either the MyMenoplan website or the following:

North American Menopause Society: <https://www.menopause.org/for-women>  
  
National Institute on Aging: <https://www.nia.nih.gov/health/topics/menopause>  
  
The Office on Women’s Health-Menopause: <https://www.womenshealth.gov/menopause>

* + **Allocation** **\*§**  
    Definition: The method by which participants are assigned to arms in a clinical trial.
    - Randomized: Participants are assigned to intervention groups by chance, they were assigned by a random number generator by birth month
  + **Enrollment** **\*estimated 300§**
* **Observational Study Design** (*For observational studies only*)
  + **Observational Study Model** **\*NA**
  + **Time Perspective** **\***  
    Definition: Temporal relationship of observation period to time of
    - Cross-sectional: Observations or measurements made at a single point in time, usually at subject enrollment

**Enrollment** **\*n=300**  
**Target Follow-Up Duration** **\*NA**

* + **Defin**ition: For Patient Registries, the anticipated time period over which each participant is to be followed. Provide a number and select a Unit of Time (years, months, weeks, days).
  + **Number of Groups/Cohorts** **\*2**
  + Definition: Number of study groups/cohorts. Enter "1" for a single-group study. Many observational studies have one group/cohort; case control studies typically have two.

 **8. Arms, Groups, and Interventions**

* **Arm Information \***(*For interventional studies only*)  
  Definition: A description of each arm of the clinical trial that indicates its role in the clinical trial; provides an informative title; and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.  
    
  Note: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.
  + **Arm Title** **\* INTERVENTION**
  + Definition: The short name used to identify the arm.  
    Limit: 100 characters.
  + **Arm Type**   
    Definition: The role of each arm in the clinical trial.
    - Experimental
* **Arm Description** **[\*]**  
  Participants are asked to spent at least 20 minutes on the website (MyMenoplan) assigned to them.
  + **Arm Title** **\*CONTROL**  
    Definition: The short name used to identify the arm.  
    Limit: 100 characters.
  + **Arm Type**    
    Definition: The role of each arm in the clinical trial.
    - Active Comparator
  + **Arm Description**
  + Participants are asked to spent at least 20 minutes on at least one of the following websites:
  + North American Menopause Society: <https://www.menopause.org/for-women>  
      
    National Institute on Aging: <https://www.nia.nih.gov/health/topics/menopause>  
      
    The Office on Women’s Health-Menopause: <https://www.womenshealth.gov/menopause>

**Group/Cohort Information** (*For observational studies only*)  
Definition: Specify the predefined participant groups (cohorts) to be studied, corresponding to Number of Groups specified under Study Design (for single-group studies, the following data elements are optional). Do not use this section to specify strata (Detailed Description can be used for that purpose, if desired).

* + **Group/Cohort Label** **\*I/C**  
    Definition: The short name used to identify the group.  
    Limit: 100 characters.
  + **Group/Cohort Description** **[\*]**  
    Definition: Explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure).  
    Limit: 999 characters.

Note: The overall study population should be described under Eligibility.

**Interventions** **\***  
Definition: Specify the intervention(s) associated with each arm or group; at least one intervention must be specified for interventional studies. For observational studies, specify the intervention(s)/exposure(s) of interest, if any. If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.

* + **Intervention Type** **\***  
    Definition: For each intervention studied in the clinical study, the general type of intervention. Select one.
    - Behavioral: For example, psychotherapy, lifestyle counseling
  + **Intervention Name(s)** **\***  
    MyMenoplan
    - **Other Intervention Name(s)** **[\*]**  
      NA
  + **Intervention Description** **\*§**  
    The goal of the intervention is to evaluate the utility of an internet-based decision tool for menopause treatment and management
* **Arm or Group/Interventional Cross-Reference** **\***  
  Definition: If multiple Arms or Groups have been specified, indicate which Interventions (or exposures) are in each Arm or Group of the study, using the Cross-Reference check boxes.

 **9. Outcome Measures**

* **Primary Outcome Measure Information** **\***  
  Definition: A description of each primary outcome measure (or for observational studies, specific key measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment).

Note: "Primary outcome measure" means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical studies have one primary outcome measure, but a clinical study may have more than one.

For each primary outcome measure, include the following information:

* + **Title**: **\*** Name of the specific primary outcome measure  
    Limit: 254 characters.
  + **Description**: **[\*]** Description of the metric used to characterize the specific primary outcome measure, if not included in the primary outcome measure title.  
    Limit: 999 characters.
  + **Time Frame**: **\*immediate – the questionnaire is completed immediately after subjects visit their assigned website(s)**
* **Secondary Outcome Measure Information** **[\*]**  
  Definition: A description of each secondary outcome measure (or for observational studies, specific secondary measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment).

Note: "Secondary outcome measure" means an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical study and is not specified as an exploratory or other measure. A clinical study may have more than one secondary outcome measure.

For each secondary outcome measure, include the following information:

* + **Title**: **\*** Name of the specific secondary outcome measure
  + **Description**: **[\*]** Description of the metric used to characterize the specific secondary outcome measure, if not included in the secondary outcome measure title.
  + **Time Frame**: **Immediate**

 **10. Eligibility**

* **Sex/Gender** **\*female**  
  Definition: The sex and, **if applicable, gender** of the participants eligible to participate in the clinical study.
  + **Sex** **\*female**  
    Definition: The sex of the participants eligible to participate in the clinical study. Select one.

Note: "Sex" means a person's classification as male or female based on biological distinctions.

* + - **Gender Based** **[\*]**  
      Definition: If applicable, indicate whether participant eligibility is based on gender. Select one.

Note: "Gender" means a person's self-representation of gender identity.

* + - * **Yes: Eligibility is based on gender**
      * **Gender Eligibility Description**  
        a non-binary person is someone who does not identify as exclusively a man or a woman.
      * A transgender male is a man who was assigned female at birth
* **Age Limits** **\***  
  Definition: The minimum and maximum age of potential participants eligible for the clinical study, provided in relevant units of time.
  + **Minimum Age** **\***40
  + **Unit of Time** **\***  
    Select one.
    - Years
  + **Maximum Age** **\***60
  + **Unit of Time** **\***  
    Select one.
    - Years
* **Accepts Healthy Volunteers** **\*§** (*Optional for Observational Studies*)  
  Yes
* **Eligibility Criteria** **\***  
  Definition: A limited list of criteria for selection of participants in the clinical study, provided in terms of inclusion and exclusion criteria and suitable for assisting potential participants in identifying clinical studies of interest. Use a bulleted list for each criterion below the headers "Inclusion Criteria" and "Exclusion Criteria".  
  Limit: 20,000 characters.

 **11. Contacts, Locations, and Investigator Information**

* **Central Contact Person** **\*** (*or Facility Contact required*)  
  Definition: The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed. Include the following information:
  + **First Name** 
    - Hui Xin
  + **Middle Initial**
  + **Last Name or Official Title** **\***
    - Ng
  + **Degree**
  + **Phone**: **8452489039**
  + **Ext**: phone extension, if needed
  + **Email**: **hxng@ucsd.edu**
* **Overall Study Officials**  
  Definition: Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator. Include the following information:
  + **First Name** Andrea
  + **Middle Initial** Z.
  + **Last Name** LaCroix
  + **Degree** PhD, Epidemiology
  + **Organizational Affiliation** University of California San Diego
  + **Official's Role**: Position or function of the official. Select one
    - Study Principal Investigator
  + **First Name** Katherine
  + **Middle Initial** M.
  + **Last Name** Newton
  + **Degree** PhD in Epidemiology
  + **Organizational Affiliation** Kaiser Permanente
  + **Official's Role**:
    - Study Co- Principal Investigator
  + **First Name** Leslie
  + **Middle Initial**
  + **Last Name** Snyder
  + **Degree** PhD, Communications
  + **Organizational Affiliation** University of Connecticut
  + **Official's Role**:
    - Study Co-Principal Investigator
* **Facility Information** **\*NA this is a web-based study**  
  **Individual Site Status** **\***  
  NA

 **12. IPD Sharing Statement**

* **Plan to Share IPD**  
  Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one.
  + Yes: There is a plan to make IPD and related data dictionaries available.
  + No: There is not a plan to make IPD available.
  + Undecided: It is not yet known if there will be a plan to make IPD available.
  + **IPD Sharing Plan Description**  
    Definition: If Plan to Share IPD is "Yes," briefly describe what specific individual participant data sets are to be shared (for example, all collected IPD, all IPD that underlie results in a publication). If the Plan to Share IPD is "No" or "Undecided," an explanation may be provided for why IPD will not be shared or why it is not yet decided.  
    Limit: 1000 characters.

If Plan to Share IPD is "Yes," provide the following information.

* + **IPD Sharing Supporting Information Type**  
    Definition: The type(s) of supporting information that will be shared, in addition to the individual participant data set and data dictionaries for the IPD itself. Select all that apply.
    - Study Protocol
    - Statistical Analysis Plan (SAP)
    - Informed Consent Form (ICF)
    - Clinical Study Report (CSR)
    - Analytic Code
  + **IPD Sharing Time Frame**  
    Definition: A description of when the IPD and any additional supporting information will become available and for how long, including the start and end dates or period of availability. This may be provided as an absolute date (for example, starting in January 2025) or as a date relative to the time when summary data are published or otherwise made available (for example, starting 6 months after publication).  
    Limit: 1000 characters.
  + **IPD Sharing Access Criteria**  
    Definition: Describe by what access criteria IPD and any additional supporting information will be shared, including with whom, for what types of analyses, and by what mechanism. Information about who will review requests and criteria for reviewing requests may also be provided.  
    Limit: 1000 characters.
  + **IPD Sharing URL**  
    Definition: The web address, if any, used to find additional information about the plan to share IPD.  
    Limit: 3999 characters.

 **13. References**

* **Citations**  
  Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.
  + **PubMed Identifier**  
    Definition: PMID for the citation in MEDLINE
  + **Citation**  
    Definition: A bibliographic reference in NLM's MEDLINE format  
    Limit: 2000 characters.
  + **Results Reference**  
    Definition: Indicate if the reference provided reports on results from this clinical study. Select Yes/No.

**Links**  
Definition: A web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

* + **URL**  
    North American Menopause Society: <https://www.menopause.org/for-women>  
      
    National Institute on Aging: <https://www.nia.nih.gov/health/topics/menopause>  
      
    The Office on Women’s Health-Menopause: <https://www.womenshealth.gov/menopause>
  + **MyMenoplan.**org

**Description**  
Definition: Title or brief description of the linked page.  
Limit: 254 characters.

* + North American Menopause Society: Official website of the North American Menopause Society   
      
    National Institute on Aging: NIA Information on Menopause  
    The Office on Women’s Health-Menopause: US Department of Health and Human Services website information on menopause
  + **MyMenoplan.**org: Website designed distilling information from MsFlash studies

**Available IPD and Supporting Information**

 **A.1 Document Upload Information**

* For details on uploading study documents (study protocol, statistical analysis plan, and/or informed consent form), see the [Document Upload Information](https://prsinfo.clinicaltrials.gov/results_definitions.html#DocumentUpload) in the Results Data Element Definitions.

 **A.2 Responsible Party Contact Information** **\*§**

* (*Provided as part of User Information or Organization Information in a PRS Account*)  
    
  Definition: Administrative information to identify and enable communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information is for the individual who is the responsible party or of a designated employee of the organization that is the responsible party. (*Will not be made public - for administrative purposes only*.)

Note: "Responsible party" means with respect to a clinical study, the sponsor of the clinical study, as defined in 21 CFR 50.3; or the principal investigator of such clinical study if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the study, has access to and control over the data from the clinical study, has the right to publish the results of the study, and has the ability to meet all of the requirements for the submission of clinical study information. For a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity who FDA orders to conduct the pediatric postmarket surveillance of the device product.

* + Name of Individual **\***
  + Official Title **\***
  + Physical Address **\***
    - Name of Organizational Affiliation **\***
    - Street Address **\***
    - City **\***
    - State/Province **\***
    - ZIP/Postal Code **\***
    - Country **\***
  + Mailing Address **\*** (*If different from Physical Address*)
    - Name of Organizational Affiliation **\***
    - Street Address **\***
    - City **\***
    - State/Province **\***
    - ZIP/Postal Code **\***
    - Country **\***
    - Phone: **\*** Use the format 800-555-5555 within the United States and Canada. Otherwise, provide the full number, including the country code.
    - Ext: phone extension, if needed
    - Email: **\*** Electronic mail address

 **History of Changes**

* January 18, 2017:  Document updated with data element changes per the FDAAA 801 final rule (42 CFR Part 11).
* February 07, 2017:  Formatting and typographical errors were corrected.
* April 18, 2017:  Added clarification that "(clinical trial)" has the same meaning as "Interventional" in Study Type and added definitions for "Yes" and "No" in U.S. Food and Drug Administration IND or IDE. Product Manufactured in and Exported from the U.S. and Outcome Measure Description definitions modified to describe when the information is required. Modified Cross-Reference element to address observational studies. Minor formatting changes.
* June 29, 2017:  Updated data elements related to Plan to Share IPD and moved to IPD Sharing Statement module. Added Document Upload Information reference (to Results Data Elements Definitions) as Appendix 1 (A.1.). Labeled Responsible Party Contact Information as Appendix 2 (A.2.). Brief Title, Study Phase - Early Phase 1, Collaborators, and Primary Purpose - Device Feasibility definitions updated with additional information to clarify meaning.
* June 27, 2018:   Typographical errors were corrected.
* March 7, 2019:   Updated Patient Registry definition to link to the most recent edition of the Registries for Evaluating Patient Outcomes: A User's Guide.
* October 1, 2020:   Increased field lengths.