

Data and Resource Sharing Checklist

Background

All NIH Collaboratory Trials will be expected to review this checklist as part of the onboarding process so they understand what will be expected. They will complete the checklist at closeout.

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all of its trials are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the [NIH Collaboratory Knowledge Repository \(KR\)](#), on a repository (eg, GitHub), or on a study website. We will link to the materials from the Living Textbook on each trial's webpage and through a separate Data and Resource Sharing section. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each trial. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from NIH Collaboratory Trials.

Data and Resource Sharing Checklist for Plan Development – Part 1

Data and Resource Sharing Checklist
1. Trial information
Trial name and acronym: <i>Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)</i>
Checklist completed by: Jessica Coifman (in collaboration with Lynn DeBar & Andrea Cook)
Date: 8/28/25
Link to ClinicalTrials.gov registration: NCT04982315
Link to trial website: <i>(retired)</i>

Data and Resource Sharing Checklist for Plan Development – Part 2

Data and Resource Sharing Checklist		
2. Resource location		
Item	Provide hyperlink or indicate if item will be stored in the KR	If item will not be shared, please provide a brief explanation for the omission
Publications/Dissemination		
Link to Protocol paper	DOI: 10.1016/j.cct.2023.107166	
Link to main outcome paper	https://doi.org/10.1001/jamanetworkopen.2025.31348	
Link to other trial-related publications	https://doi.org/10.1016/j.cct.2025.107981 https://doi.org/10.1177/21649561211007091 https://doi.org/10.1177/27536130251340921 https://doi.org/10.1093/jamia/ocab202 https://doi.org/10.1016/j.cct.2023.107426 https://doi.org/10.1016/j.imr.2024.101042	<p><i>We also have manuscripts in review or under development that happy to share when published including:</i></p> <p>Herman et al. Cost-effectiveness of acupuncture needling for older adults with chronic low back pain.</p> <p>Wellman et al. Session dose and adherence related to dysfunction and pain: Results from the BackInAction trial.</p> <p>DeBar et al. Reflections of national key informants and acupuncturists about Medicare reimbursement parameters and alignment with real world care.</p> <p>Mu et al. Effects of acupuncture on sleep and fatigue in older adults with chronic low back pain: Findings from the BackInAction pragmatic clinical trial.</p>
Materials used to communicate overall trial results to participants (eg, lay summary)	N/A	We are exploring feasibility of preparing and sending lay summary out and will send on the summary if prepared and disseminated.
Study tools		
Final version of the protocol, including summary of changes	Plan to upload to KR: BackInAction Trial Protocol	

Consent documents or consent process	N/A	Variability in consents across sites suggests unlikely transferability
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)	Plan to upload to KR: Acupuncturist Treatment Manual	
Participant-facing materials (eg, videos, flyers, handouts)	N/A	
Computable phenotypes for outcome measures	N/A	
Computable phenotypes for the inclusion/exclusion criteria	N/A	
Code for generating variables in the analytic dataset from standard sources	N/A	
Datasets and documentation		
Annotated data collection forms	Plan to upload to KR: -Baseline Assessment -1-Month Assessment -Monthly Assessment -3-Month Assessment -6-Month Assessment -12-Month Assessment	
Link to public use dataset	We prepared a public use dataset of our study baseline and outcomes data along with data specifications (aligned with HEAL common data elements when possible) to be posted on the NIMH Data Archive (NDA) repository under collection ID 5670 . This dataset includes trial data from three of the four project sites; KPNC-IRB did not grant approval for data sharing to the NDA. KPNC data can be requested for future research collaborations with BackInAction investigators. NIMH Data Archive - Data - Collection	
Data dictionary (proc contents) for public use dataset	Data Dictionary can be found here: NIMH Data Archive - Data - Collection	
Other resources		
Statistical Analysis Plan	Plan to upload to KR	