

Data and Resource Sharing Checklist

Background

All NIH Collaboratory Trials will be expected to review the attached 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 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](#), in another 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 Knowledge Repository, contact nih-collaboratory@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 accompanying Data Sharing Information Document, the Electronic Health Records Core provides a partial list of existing data sharing platforms. The 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 the NIH Collaboratory Trials.

Data and Resource Sharing Checklist – Part 1

1. Trial information

Trial name and acronym: Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)

Checklist completed by: Jessica Coifman (in collaboration with Lynn DeBar & Andrea Cook)

Date: 08/28/2025

Link to ClinicalTrials.gov registration: [NCT04982315](#)

Link to trial website: Retired

Data and Resource Sharing Checklist – Part 2

2. Resource locations		
Item	Provide hyperlink or indicate if item will be stored in the Knowledge Repository	If item will not be shared, please provide a brief explanation for the omission
Publications/dissemination		
Link to study design paper or protocol paper	DeBar et al (PMID: 36990274)	
Link to main outcome paper	DeBar et al (PMID: 40938602)	
Link to other trial-related publications	All BackInAction publications	
Materials used to communicate trial results to participants (such as plain-language summaries)	Not applicable	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 protocol, including summary of changes	BackInAction protocol	
Consent documents or description of consent process	Not applicable	
Tools for sites (such as toolkits, checklists, instruction sheets, and clinician-facing materials)	Not applicable	
Participant-facing materials (such as videos, flyers, and handouts)	Not applicable	
Computable phenotypes for outcome measures	Not applicable	
Computable phenotypes for inclusion/exclusion criteria	Not applicable	
Code for generating variables in the analytic dataset from standard sources	Not applicable	
Datasets and documentation		
Annotated data collection forms	BackInAction data collection forms	
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	

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	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	NIMH Data Archive - Data - Collection	
Other resources		
Statistical analysis plan	BackInAction statistical analysis plan	