Evaluating Methodological Integrity in Reconsolidation Research: A Systematic Review

Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
Included RCT Metadata	Data extracted from eligible RCTs, including sample size, intervention type, memory reactivation procedure, outcomes, preregistration details	*Reused*	Digital	Numerical and textual: Observational metadata	.xlsx, .csv	~50MB	x
Quality Assessment Data	RoB 2 assessments for each RCT, including domain-level judgments and overall bias	Newly Generated	Digital	Numerical and textual: Evaluation data	.xlsx, .csv, .docx	~10MB	x
Protocol Adherence Ratings	Data on preregistration compliance, outcome reporting, and methodological deviations	Newly Generated	Digital	Numerical and textual: Qualitative and categorical	.csv, .docx	~10MB	x
Effect Size Calculations	Extracted or calculated effect sizes (e.g., Cohen's d) and CI for symptom reduction	Newly Generated	Digital	Numerical: Quantitative/statistical	.xlsx, .R	~10MB	x
Narrative Notes	Observational summaries and qualitative synthesis notes during review	Newly Generated	Digital	Textual	.docx	~10MB	x
Covidence Screening Logs	Screening decisions, reviewer agreement, inclusion/exclusion logs	Newly Generated	Digital	Textual: Process logs	.csv, .docx	~10MB	x

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

- Published RCTs retrieved from: PubMed, Embase, PsycINFO(via OVID), CENTRAL, Web of Science, ClinicalTrials.gov
- Persistent IDs: DOIs of each included study will be collected and documented per record.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- No

No primary data will be collected from human participants. Only secondary data (published or preregistered RCTs) will be analyzed.
No ethical approval required for reuse of publicly available, published data.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- No

No personal data will be processed.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

All reused data is from published articles. Proper citation (including DOIs) will be maintained.
No ownership or intellectual property rights issues apply.

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

To ensure that all datasets are understandable, transparent, and reusable both during the project and after its completion, the following documentation practices will be implemented:

1. **README Files:**
    - A dedicated README file will accompany each dataset or dataset folder.
    - Each README will contain:
        - **Title and short description** of the dataset (e.g., “Effect Size Calculations from Reconsolidation-Based RCTs”).
        - **Date of creation or update**, version number, and author(s) responsible for that dataset.
        - **Purpose of the dataset** (e.g., "Contains all extracted symptom effect sizes used for meta-analysis").
        - **Detailed explanation of each variable** or column in the dataset (e.g., “effect_size_d = Cohen’s d; group_n1 = sample size of intervention group”).
        - **Units of measurement**, missing data codes (e.g., NA, NULL), and how they were handled.
        - **Software used to create or process the data** (e.g., “R v4.3.1 with metafor package”).
        - **Reference to related documents**, such as the data extraction form or codebook.
        - **Instructions for re-use**
2. **Codebook (.tsv or .xlsx format):**
    - A structured **codebook** will be created for the main data extraction sheet (i.e., the metadata extracted from RCTs).
    - This file will contain:
        - **Variable names**
        - **Variable labels**
        - **Data type** (e.g., string, integer, categorical)
        - **Value labels** (e.g., “1 = pharmacological; 2 = behavioral”)
3. **Covidence Logs:**
    - Covidence will be used for title/abstract screening, full-text screening, and conflict resolution.

- Exported logs from Covidence (in .csv or .docx/.pdf format) will document:
  - **Inclusion/exclusion decisions**
  - **Reviewer agreement statistics**
  - **Reasons for exclusion**
  - **Timestamps and reviewer IDs**

4. **Zotero Metadata Archive:**
   - All references (included and excluded studies) will be organized in a **Zotero library**, tagged by screening status (e.g., "included_fulltext", "excluded_population"), with notes detailing inclusion/exclusion justifications.
   - Each item in Zotero will include:
     - Complete citation
     - Persistent identifier (e.g., DOI)
     - PDF attachment (where available)
     - Link to ClinicalTrials.gov or OSF registration (where applicable)
     - Manual notes on key methodological aspects (e.g., reactivation method, intervention timing)
5. **Preregistration Adherence Logs:**
   - A separate documentation file (e.g., preregistration_compliance.docx) will be maintained, summarizing:
     - Whether the study was preregistered
     - Which registry it was found in (e.g., ClinicalTrials.gov, WHO, OSF)
     - Whether primary/secondary outcomes were reported as planned
     - Whether any deviations were explained or justified
6. **Reconsolidation Criteria Adherence Assessment Sheet (.xlsx):**
   - A dedicated document (reconsolidation_criteria_assessment.xlsx) will be created to systematically evaluate each included RCT against the predefined **reconsolidation criteria** outlined in the protocol (e.g., Memory Consolidation, Reactivation, Post-Reactivation Intervention Timing, etc.).
     For each study, reviewers will indicate:
     - **Whether each criterion is fulfilled** (Yes/No/Unclear),
     - **Supporting evidence from the text** (e.g., quotes or figure references),
     - **Reviewer comments or justifications**, and
     - An overall **adherence score or classification** (e.g., High, Moderate, Low).

Any update to datasets (e.g., adding new studies, corrections) will be logged with date, reason for change, and author initials.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

To ensure clarity, transparency, and future reusability of all datasets, this project will follow the **PRISMA 2020 reporting standard** and maintain structured documentation throughout the review process.
All documentation and metadata associated with this project will align with the **PRISMA 2020 Statement** guidelines for systematic reviews. This includes:

- **Eligibility Criteria Documentation**
  A detailed .docx file outlining all inclusion/exclusion criteria used during study selection, consistent with PRISMA Item 5.
- **Search Strategy Documentation**
  A .pdf file containing the full search strings for each database, with syntax tailored to each platform (PubMed, Embase, PsycINFO, CENTRAL, etc.), per PRISMA Item 7.
- **Study Selection and Flow Diagram**
  A PRISMA 2020-compliant flowchart (.png and .pdf) showing the number of studies at each stage of screening, generated via Covidence or manually created in accordance with PRISMA Item 16a.
- **List of Excluded Studies**
  A .csv file listing all full-text studies excluded after screening, with justifications for exclusion (Item 16b).
- **Data Extraction File (Main Dataset)**
  An .xlsx file that includes all key extracted variables for included RCTs:
  - Author, year, country

- Population and sample size
- Intervention type (pharmacological/behavioral)
- Memory reactivation method
- Timing of intervention
- Symptom measures and outcomes
- Adherence to reconsolidation criteria
- Preregistration status and deviations
- Effect sizes and statistical outcome

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Sharepoint online
- Other (specify below)

KU Leuven OneDrive and KU Leuven secured servers.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Access is already restricted to research team via KU Leuven institutional login. Files will be encrypted where necessary.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Covered by institutional infrastructure, no additional costs.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- KU Leuven RDR

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

No costs expected; repositories are free for academic use or covered by institution.

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as open data

We will share:

- Extracted datasets
- Risk of bias scores
- Checklist adherence ratings
- Effect sizes
- Search strategy

If access is restricted, please specify who will be able to access the data and under what conditions.

It will be public, via OSF (or similar open access platform) and linked to publication (DOI).

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

None. However, individual RCT full-texts will not be redistributed.

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)
- Other data repository (specify below)

OSF (https://osf.io), Lirias (KU Leuven), PROSPERO (registration)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

None expected for sharing; covered by open access platforms.

Responsibilities

Who will manage data documentation and metadata during the research project?

Lora Čuljak (lora.culjak@kuleuven.be)
additionally: Tom Beckers (tom.beckers@kuleuven.be)

Who will manage data storage and backup during the research project?

Lora Čuljak (lora.culjak@kuleuven.be)
additionally: Tom Beckers (tom.beckers@kuleuven.be)

Who will manage data preservation and sharing?

Lora Čuljak (lora.culjak@kuleuven.be)
additionally: Tom Beckers (tom.beckers@kuleuven.be)

Who will update and implement this DMP?

Lora Čuljak (lora.culjak@kuleuven.be)
additionally: Tom Beckers (tom.beckers@kuleuven.be)