Plan Overview

A Data Management Plan created using DMPonline

Title: A Systematic Review of The Relationship Between Type I Diabetes and Sleep in Children and Young People and Their Families.

Creator: Beatriz De Ribas E Venâncio

Principal Investigator: Beatriz De Ribas E Venâncio

Data Manager: Beatriz De Ribas E Venâncio

Project Administrator: Beatriz De Ribas E Venâncio

Contributor: Gurprit Lall, Rachel Besser, Jakke Tamminen, Alice M. Gregory

Affiliation: Royal Holloway, University of London

Funder: Economic and Social Research Council (ESRC)

Template: Royal Holloway - Institutional template Nov 2024

ORCID iD: 0009-0009-4043-267X

Project abstract:

Type 1 diabetes (T1D) requires continuous and intense management, including continuous glucose monitoring and insulin administration. Existing research recognises the association between this demanding condition and disrupted sleep for both children and young people (CYP) and their caregivers; yet evidence remains inconsistent, with some studies showing minimal or no objective differences in sleep architecture between children living with T1D and their peers without T1D. Developing a systematic understanding of how these factors interact is crucial to inform future research and potentially guide clinical interventions, specifically by extending the analysis to caregivers and siblings without diabetes, populations often neglected in the existing body of literature.

Considering the above, this project is a mixed-methods systematic review (with the possibility of a meta-analysis) examining the association between T1D and sleep in CYP living with T1D, their caregivers and their siblings. Guided by the SPIDER framework (Sample, Phenomenon of Interest, Design, Evaluation, Research type; Cooke et al., 2012), our review will address two condensed questions: (1) How do sleep outcomes and experiences differ between families living with T1D and those without (including the CYP with T1D, caregivers and siblings without T1D)? (2) Within CYP with T1D and their families, how do sleep outcomes vary across different treatment modalities (e.g., multiple daily injections, insulin pumps, and hybrid closed-loop systems)?

The review was prepared according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA, Page et al., 2021) and the knowledge synthesis principles outlined by Tricco et al. (2011) (Tricco et al., 2022). MEDLINE, EMBASE, PsycINFO, and

Cochrane are the selected databases for our search. Searches of clinical trial registries (ClinicalTrials.gov and WHO ICTRP) will also be conducted. Data management will employ Zotero, Rayyan, Excel, and NVivo, Dropbox for business, with potential quantitative synthesis using R and RStudio. In alignment with open science principles, the protocol will be preregistered in the Open Science Framework (OSF) repository, in the Royal Holloway Data Repository, in the researchers' PURE profile, and a preprint will be available on medRxiv.

ID: 189975

Start date: 01-10-2025

End date: 01-10-2026

Last modified: 12-01-2026

Grant number / URL: N/a

Copyright information:

A Systematic Review of The Relationship Between Type I Diabetes and Sleep in Children and Young People and Their Families.

Administrative Data

Please define an ID for your DMP.

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Which funder are you applying to?

N/a.

What is the title of your project?

A Systematic Review of The Relationship Between Type I Diabetes and Sleep in Children and Young People and Their Families.

Briefly describe your project.

To complement our abstract, here we will present an in-depth definition of our research questions. The primary research questions are as follows:

1. How do sleep outcomes and experiences differ between CYP living with T1D and their npeers without T1D?
2. How do sleep outcomes and experiences differ between parents of CYP living with T1D and parents of CYP without T1D?
3. How do sleep outcomes and experiences differ between siblings of CYP living with T1D and siblings of CYP without T1D?

In addition to the primary research questions, this review will examine the following secondary questions:

1. Amongst CYP living with T1D, how do sleep outcomes differ between those treated with multiple daily injections (MDI), those using insulin pumps, and those using closed-loop systems?
2. Amongst parents of CYP living with T1D, how do sleep outcomes differ between those treated with MDI, those using insulin pumps, and those using closed-loop systems?
3. Amongst siblings CYP living with T1D, how do sleep outcomes differ between those treated with MDI, those using insulin pumps, and those using closed-loop systems?

Who is the primary investigator on the project? Please also name any co-investigators on the project.

The primary investigator is Beatriz Venâncio (PhD student). The co-investigators are Dr Alice Gregory, Dr Jakke Tamminen, Dr Rachel Besser, Dr Gurprit Lall, and undergratuate volunteer research

assistants.

Who is the project data contact?

Beatriz.Venancio@live.rhul.ac.uk

Data Collection

What types of data/ files will be created?

Throughout the review process, we will generate bibliographic, quantitative, qualitative, and administrative data. Search results exported from electronic databases will be stored in RIS and XML formats and managed in Zotero for deduplication. Screening records will be maintained in Rayyan and exported to Excel spreadsheets, providing a transparent record of inclusion and exclusion decisions. Data extraction will produce structured qualitative coding files and possibly quantitative datasets. Qualitative and mixed-methods data will be managed and coded in NVivo. If feasible, quantitative data and metadata will be recorded in Microsoft Excel and, where applicable, analysed using R. All supplementary materials (e.g., extraction templates, codebooks, instructions, and protocol documentation) will be prepared in Word, PDF, or CSV.

All data outputs will adhere to the FAIR principles (findability, accessibility, interoperability, and reusability, Wilkinson et al., 2016). To ensure findability, all datasets and accompanying metadata will be deposited in the project's Open Science Framework (OSF) repository, and the registration will be assigned a digital object identifier (DOI). Accessibility will be supported by providing open access to non-sensitive materials without embargo, using widely readable, non-proprietary file formats. Interoperability will be achieved by maintaining consistent variable naming, adhering to metadata standards, and using file formats compatible with major bibliographic and analytical software. Finally, reusability will be ensured through comprehensive documentation and version control.

What is the estimated total volume of data, number of items / files and largest individual file / items size?

The estimated total volume of data for this project is expected to be moderate, aligned with the nature of a systematic review in which most materials are text-based. The total volume is estimated at approximately 5-10 GB. Across all stages of the review, an estimated 150-250 individual files will be generated, the largest individual items are expected to be the NVivo project file and the Zotero reference library, each ranging from roughly 300 MB to 1 GB.

How will the data be collected or created?

Data will be collected and created through a transparent, pre-registered systematic review process following the PRISMA 2020 statement (Page et al., 2021) and the knowledge synthesis principles described by Tricco et al. (2011) (Tricco et al., 2011). Search strategies were developed in consultation with a subject librarian to ensure precision and reproducibility, and all search queries will be documented verbatim. Records will be exported directly from electronic databases (MEDLINE, EMBASE, PsycINFO, and Cochrane) in RIS or XML format, imported into Zotero for de-duplication, and

transferred to Rayyan for screening. Screening decisions, inclusion and exclusion justifications, and inter-rater agreement data will be logged in structured Excel spreadsheets. Data extraction will then proceed using predefined templates piloted for consistency across reviewers. Qualitative and mixed-methods data will be coded and managed in NVivo to support thematic synthesis while quantitative variables will be extracted into Microsoft Excel and cross-checked by a second reviewer.

Will any existing research data be used? If yes, describe any actions that will need to be taken in order to gain access to this data.

No existing research data requiring access permissions will be used in this project.

Are there any special tools and/or software needed to work with or view the data? If yes, describe any actions that will need be taken to access these tools or software.

Yes, five specialised software tools will be used to manage, screen, and analyse the data, all of which are either open access or covered by existing university licences. Reference management and de-duplication will be conducted using Zotero, while Rayyan will support blinded screening and reviewer collaboration (both open-access). Data extraction and management will take place in Microsoft Excel 365, available through the institutional Microsoft 365 account. Qualitative and mixed-methods data will be organised and coded in NVivo 14, for which the university provides a site licence. If quantitative synthesis or sensitivity analyses are required, these will be performed in R (version 4.3.2) using open-source packages such as *meta*, *metafor*, and *robvis*. This approach guarantees full reproducibility and sustainability of the data workflow within institutional and open-science frameworks.

Documentation and Metadata

What documentation and metadata will accompany the data?

Each dataset uploaded in the OSF repository will include metadata describing the project title, contributing authors, institutional affiliations, date of creation and software environment. This will be created and maintained in accordance with the DataCite Metadata Schema (v4.5, Liffers et al., 2024).
Accompanying documentation will also include the methodological and analytical context of the review, including the search strategy, inclusion and exclusion criteria, extraction templates, coding frameworks, screening and extraction instructions, and data transformation logs. Variable definitions, abbreviations, and units of measurement will be compiled in a dedicated data dictionary. Qualitative codebooks will outline the structure and meaning of themes developed during analysis.

Ethics and Legal Compliance

Have you completed the University Ethics review process?
A DMP must be created and attached to the research ethics application. This process is

only required after a project has been awarded or the research activity has been approved.

Yes. Ethical approval was provided on the 28/11/2025 (Ref. 871).

How will any ethical aspects related to RDM and / or highlighted in the Ethics process be managed?

No significant ethical concerns are anticipated for this project. Ethical integrity in research data management (RDM) will be maintained through adherence to principles of transparency, accuracy, and adequate attribution of all sources. All extracted information will remain at the aggregate level and will be managed in accordance with institutional research ethics guidance and open-science best practices.

How will any personal identifying data be kept separately to responses?

N/a.

Who will own the copyright of the research data?

Copyright for the research data and documentation generated in this project will rest with all authors, Royal Holloway, and collaborating institutions. Any publications resulting from the project may be subject to publisher copyright transfer agreements, but the underlying datasets and supporting documentation will remain the property of the researchers.

Are there any specific copyright / IP aspects that need to be considered?

No complex copyright or intellectual property issues are anticipated, as the project relies exclusively on data extracted from published and publicly accessible studies rather than generating new primary datasets.

Storage and backup during the research

How will the data be stored and backed up during the research?

Active project files, including bibliographic databases, screening records, extraction sheets, and NVivo project files, will be stored in Dropbox.com and local (password protected) drives. This platform provides automatic, encrypted cloud backups and complete version control, ensuring recoverability in the event of accidental deletion or system failure. Local copies of working files will also be maintained on the researchers' password-protected laptops. Data will therefore exist in at least three secure, encrypted locations at all times. In the unlikely event of a system failure or data loss, recovery will be managed through Dropbox's restore function and, if necessary, supported by Royal Holloway IT

Services. No sensitive or personal data will be collected or stored, as the review is based solely on published studies. All files will be stored and processed within systems compliant with UK GDPR and ISO 27001 information security standards. The final datasets and documentation will be uploaded to the OSF repository for long-term archiving and public access, while institutional backups will remain available through Royal Holloway's managed storage.

How will you manage access and security during the research?

Because our project does not involve any personal, confidential, or commercially sensitive data, the primary focus of security management will be to maintain the integrity and traceability of project files. Access to active data stored in Dropbox will be restricted to the researcher team password-protected, permission-controlled folders. Two-factor authentication will be enabled for all institutional accounts. External collaborators and will be granted access through authenticated institutional credentials only. File naming conventions, clear folder hierarchies, and version control will be maintained to prevent data loss or duplication.

Will the data be shared and accessed by other collaborators, colleagues etc during the research? If yes, how will this be managed?

Yes, selected data and project materials will be shared with supervisors and approved external collaborators via secure, institution-approved cloud storage (e.g., Dropbox for Business or equivalent). Access will be managed through permission-controlled folders and restricted to authorised individuals only. Data sharing with external collaborators will be covered by appropriate data-sharing or collaboration agreements between institutions, and all collaborators will receive clear guidance on data handling, confidentiality, and version control. No external collaborators or third parties will have access to active project files unless formally approved by the supervisory team, and access will be reviewed and revoked when no longer required.

Evaluation and retention

Which data needs to be retained after the research ends?

Following completion of the research, all materials essential for transparency, reproducibility, and potential reuse will be retained and preserved. This will include the final extraction datasets (CSV/XLSX), screening logs, data dictionaries, search strategies, coding frameworks, and qualitative synthesis outputs. Draft or redundant files will be securely deleted. The retained datasets and documentation will be deposited in the OSF repository, which provides long-term preservation and a persistent DOI.

Where will this retained data be stored?

All retained data will be stored in the project's OSF repository. A secure copy will also remain within Royal Holloway's institutional storage (Royal Holloway Data Repository) to ensure redundancy and

compliance with university data retention policies.

How long will the data be kept for?

In line with ESRC guidelines, these materials will be preserved for a minimum of 10 years after project completion to allow for validation, replication, and secondary analyses.

Does any data need to be destroyed / deleted? If yes, how will this be managed and by who and when?

Not aplicable beyond files for redundant drafts or incomplete working versions.

Data Sharing after research ends

Which data will need to be shared?

To complement the previous sections, all data with long-term value (i.e., final extraction sheets, screening logs, search strategies, and synthesis documentation) will be shared openly through the OSF repository. Each dataset will receive a persistent DOI, enabling citation, discoverability, and compliance with FAIR principles. Metadata and documentation will ensure users can interpret and reuse the materials appropriately. Data will become publicly available upon the completion of the study, with immediate open access for some accompanying documentation (i.e., protocol, instructions, data management plan) once pre-registration on OSF is completed. Links and data availability statements will be included in all research outputs to direct users to the OSF repository.

Because Dropbox permissions may expire after the doctoral registration period (2025-2029), in addition to the OSF repository, we will also transfer the files to Royal Holloway's Data Repository. Our project does not involve confidential or restricted data; therefore, no data-sharing agreements or embargoes will be required.

Where will this data be stored?

OSF repository, Royal Holloway data repository (*Figshare* for institutions) and Dropbox (while permissions are in place).

How will the data be shared eg considerations around Open Access, terms of reuse and licencing?

Data will be shared through the Open Science Framework.

Where will the location of the data be recorded?

The location of all deposited datasets will be recorded in the thesis, associated publications' data availability statements, and the project's OSF repository.

Has consent been acquired /agreed from participants to share the data?

N/a.

Are any restrictions on data sharing required?

No, we do not expect any restriction on data sharing to be required.

Responsibilities and Resources

Who will be responsible for research data management?

The PhD researcher (BV) will be responsible for implementing the Data Management Plan and ensuring that all data management activities are conducted in line with Royal Holloway's Research Data Management Policy and ESRC guidelines.

What resources will you require to deliver your plan?

The resources required to deliver this Data Management Plan are fully covered by existing Royal Holloway and ESRC studentship provisions. All necessary software is either open access or available through institutional licences. Data storage, security, and backup will be supported by Dropbox for Business and long-term preservation via the Open Science Framework and Royal Holloway Figshare for Institutions, both of which are free to use.

State any identified costs and sources of funding for resources.

N/a.

Please outline the actions that you will take to manage the research data when the project ends / before leaving the University

In addition to the aforementioned repositories, local and cloud copies will be verified for completeness, securely backed up, and any redundant or temporary files will be deleted. Supervisors will be notified once all data are archived to ensure compliance with university data retention requirements.

Who will manage the research data after project end / after the PI leaves the University to continue to meet any requirements?

After project completion, the archives will be managed by Royal Holloway, University of London.