Supplementary Material
Invitation to Collaborate authors and Template Data Sharing Agreement including Data Requested

A) Text of letter to potential collaborators

Dear
Thank you for agreeing to collaborate with our individual patient data meta-analysis of interventions for self-harm. We are nearly ready to start formal data sharing and so need you to sign and return the formal data sharing agreement attached to this letter.
This formal agreement provides assurance about data confidentiality and security, what we will and will not do with any shared data, intellectual property etc. Schedule 2 sets out the data we would like you to share and how we would like you to anonymise it.
Please note, that

a) we do not want you to share any data just yet. Once we have a signed agreement, we will be in touch about the practicalities of secure data transfer; and
b) if you are unsure about sharing some of the data listed please get back to me as we may be able to agree transfer of a smaller data set

In the UK this sort of data sharing agreement is common practice, and a senior manager in the University will usually need to sign it, not a study chief investigator like myself. I am sure different arrangements will apply in different countries, and I appreciate you may need some time to establish who in your institution has authority to sign this.
We would prefer to use this form of agreement but if your institution has its own template for data sharing and wishes to use, it please let me have a copy I will attempt to get my University to agree to its use.
If you are still content to proceed, all that is needed is to complete your Institution's name and address at the top of the first page, and enter your Institution's name and an appropriate signature at the bottom of page 4.
I remain very grateful that you are willing to make time to help with this project. If you have any questions, please ask. I am confident that once we can move past this governance/ legal stage, the analysis itself will be fascinating and have the potential to answer a number of important and clinically relevant questions. I look forward to working with you on those questions.
With best wishes

Yours sincerely

B) Template Data Sharing Agreement

RESEARCH DATA DISCLOSURE AGREEMENT

This Agreement is made by and between:

PARTIES

(1) **UNIVERSITY OF LEEDS** whose principal place of business is Leeds, LS2 9JT, United Kingdom ("**UOL**");

AND

(2) **<<Institution name>>** whose principle place of business is <<Institution address>> ("**Institution**").

UOL and the Institution are individually referred to as a **Party** and collectively known as the **Parties** to this Agreement.

BACKGROUND

A. UOL via the Leeds Institutes of Health Sciences and Clinical Trials Research at UOL is undertaking research on Self Harm titled ***ReducIng Self-Harm in Adolescents: Individual Patient Data meta-analysis (RISA-IPD*** **("Study")** further details of which are available in Schedule 1

B. Schedule 2 contains details of certain data to be transferred by the Institution to the UoL ("**Data**") for the purposes of conducting the Study.

C. Results derived or developed in the Study from the Data shall be owned by UoL ("**Results**").

AGREED TERMS

1. Data Supply

1.1. Institution will provide the Data to UOL in the format specified in Schedule 2.

1.2. The Institution undertakes, warrants or represents that the Data is of satisfactory quality, fit for purpose, corresponds to description in Schedule 2 and that the Data will not infringe the intellectual property rights of any third party.

2. Confidentiality

2.1. The UOL will, using reasonable endeavours, ensure that the Data is used only by UOL staff working on the Study and only for the purpose of the Study and is not passed to anyone outside of the Study without the prior written consent of Institution.

2.2. UOL will, using reasonable endeavours, ensure the security of the Data and that it is treated as confidential. In particular UOL will ensure that:

2.2.1. Data remains confidential as governed by common law obligations of confidentiality and/or medical confidentiality, requirements of the

Data Protection Act 2018, the Human Tissue Act 2004, any other applicable laws, each as amended from time to time;

2.2.2. No attempt is made by UOL to re-identify, trace or contact the Study subjects, or to access data which could identify the Study subjects, or to use the Data in any way that could infringe the rights of the Study subjects, or otherwise affect them or the Study adversely;

2.2.3. Data is stored only on a computer system to which access is password protected for an account which can only be accessed by staff working on the Study, and for which only they know the password;

2.2.4. Current anti-virus, anti-malware and encryption software is installed on all systems and hardware being used to store or access Data;

2.2.5. UOL shall not export nor permit the Data to be exported from the United Kingdom;

2.2.6. UOL reports to Institution immediately when UoL becomes aware of any breach of this clause 2.2.

2.3. UOL will ensure that the Data is used only by the staff working on the Study and only for the purpose of the Study and is not passed to anyone outside of the Study without the prior written consent of Institution.

2.4. UOL will ensure that any regulatory ethics committee approvals required for use of the Data in the Study are obtained before the Data is used.

2.5. UOL will ensure that the Data is used in compliance with all applicable law including without limitation the Data Protection Act 2018.

2.6. Parties to this Agreement which are subject to the Freedom of Information Act 2000 ("**FOIA**") or the Freedom of Information (Scotland) Act 2002 ("**FOI(S)A**") or any equivalent legislation in another jurisdiction ("**Equivalent**") and which receive a request under FOIA or FOI(S)A or an Equivalent to disclose any information that belongs to the other Party will notify and consult that Party in writing as soon as reasonably practicable, and in any event, not later than five working days after receiving the request. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under FOIA or FOI(S)A or Equivalent is a decision solely for the Party responding to the request. Where the Party responding to an FOIA or FOI(S)A or Equivalent request determines that it will disclose information that belongs to the other Party it will notify the other Party in writing, giving at least five working days' notice of its intended disclosure.

3. Data ownership, Intellectual Property

3.1. <<Institution>> are the Controller of the Data and the owner of any intellectual property rights subsisting in the Data.

3.2. UOL will own the Study results (including data generated by the Study) ("**Results**") and any intellectual property rights subsisting in the Results. UOL will license back any new (foreground) intellectual property to the original custodians for non-commercial use.

4. Publication

4.1. UOL will acknowledge Institution's contribution in any publication (including posters and abstracts) of the Results as follows: i) by identifying a named collaborator from Institution to work with the UOL research team and, if that person so chooses, including them as an author in any publications of primary results from the research, provided that they meet the requirements of the International Committee of Medical Journal Editors. Every effort will be made to offer the named collaborator opportunities to meet these requirements. ii) by referencing in the primary study publication, the publication summarising the Institution's work.

4.2 UOL will provide Institution with a copy of any proposed presentation, poster, abstract or other publication involving the Results twenty-one days in advance of the submission date and will remove information that is considered by Institution to be confidential and/or potentially damaging to the Study subjects or is an infringement of IP rights or other contractual terms which the Institution is bound by.]

5. Term and Termination

5.1. This Agreement will commence on the date of the last signature to this Agreement and will terminate on completion of the Study; or

5.2. Either Party may terminate this Agreement with immediate effect at any time by notice in writing to the other Party if the other Party is in material breach of this Agreement and, if remediable, the breach is not remedied within thirty days of the other Party receiving written notice of it.

5.3. On termination of this Agreement, the UOL will destroy any copy of the Data supplied by Institution and any copies made subsequently by UOL. For the avoidance of doubt, no copies of the Data may be retained by UOL other than Data embedded in Results and any Data captured in the course of the UOL's routine computer system back-up procedures which may only be used for the purpose of using the Results and for back-up purposes respectively. Upon notification by Institution to UOL, at any time, that one or more Study subjects have withdrawn their consent for the continued use of their Data, UOL will destroy those parts of the Data identified by Institution. UOL will retain its own database of integrated and transformed data for a minimum of 5 years after completion of the research.

5.4. Upon termination the following clauses will continue in force: clauses 1.2, 3, 4, 5.3, this 5.4 and 6 to 8 inclusive.

6. Notices

6.1. Contact for notices:

For UOL	For the Institution
Director of Commercialisation Research & Innovation Service Worsley Building University of Leeds Leeds, LS2 9JT	[INSERT NAME OR JOB TITLE IN CONTRACTS ADMINISTRATION, ADDRESS AND TEL/FAX]

6.2 All notices will be in the English language.

7. Disputes, Governing Law and Jurisdiction

7.1. This Agreement will be subject to and construed and interpreted in accordance with English law and will be subject to the exclusive jurisdiction of the Courts of England. This clause 7.1 shall not prevent a party from seeking interim relief in any court of competent jurisdiction.

7.2. If any dispute arises in connection with this Agreement, directors or other senior representatives of the Parties with authority to settle the dispute will, within thirty days of a written request from one Party to the other, meet (or speak by telephone) in a good faith effort to resolve the dispute.

7.3. If the dispute is not resolved at that meeting, the Parties will attempt to settle it by mediation in London in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure. Unless otherwise agreed between the Parties, the mediator will be nominated by CEDR. To initiate the mediation a Party must give notice in writing ("**ADR notice**") to the other Party to the dispute requesting a mediation. A copy of the ADR notice should be sent to CEDR Solve. The mediation will start not later than sixty days after the date of the ADR notice. No Party may commence any court proceedings in relation to any dispute arising out of this Agreement until it has attempted to settle the dispute by mediation and either the mediation has terminated or the other Party has failed to participate in the mediation, provided that the right to issue proceedings is not prejudiced by a delay and provided that this will not prevent a Party from seeking interim relief from court.

8. General

8.1. This Agreement is personal to the Parties and no Party will, without the prior written consent of the other Party, assign, transfer, mortgage, charge or deal in any manner with this Agreement or any of its rights and obligations under this Agreement, or purport to do any of the same. No Party will subcontract or

delegate in any manner any or all of its obligations under this Agreement to any third party or agent.

8.2. Each Party is acting on its own behalf and not for the benefit of another person.

8.3. No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.

8.4. If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision will, to the extent required, be severed from this Agreement and will be ineffective without, as far as possible, modifying any other clause or part of this Agreement and will not affect any other provisions of this Agreement which will remain in full force and effect.

8.5. No amendment of the terms of this Agreement shall bind either Party unless in writing and signed by both Parties.

8.6. This Agreement may be executed in any number of counterparts, each of which when executed and delivered will constitute an original of this Agreement, but all the counterparts will together constitute the same Agreement.

Signed for and on behalf of University of Leeds

Title
Date

Signed for and on behalf of the <<Institution>>

Title
Date

Schedule 1

The Study

To conduct an individual patient data meta-analysis (and meta-regression) of existing randomised controlled trials of therapeutic interventions to reduce subsequent self-harm in adolescents in order to identify subgroups of adolescents in whom a therapeutic intervention for self-harm shows some evidence of benefit (or dis-benefit).

Plan of Investigation

To perform an updated and refined systematic literature search to select published and unpublished randomised controlled trials of therapeutic interventions to reduce subsequent self-harm in adolescents who have already self-harmed and presented to services.

Authors of identified eligible studies will be contacted and invited to share individual-participant-data (IPD) and collaborate with us. IPD will be securely transferred to the statisticians in Leeds. Where IPD is not available, we will use (published) aggregated data. After data cleaning and manipulation, we will conduct a meta-analysis and meta-regression of data from each trial.

Potential Impact

If the meta-analysis indicates clearly that certain sub-groups of young people do better (or worse) with certain types of intervention, we would expect significant changes in the way that services are delivered to those groups of young people. If the evidence is less clear-cut it is possible that avenues of future research are suggested using more tailored interventions for sub-groups of young people, leading to new and better targeted randomised controlled trials to confirm (or refute) the hypotheses raised by our results[1].

1. See the project web page at https://medicinehealth.leeds.ac.uk/dir-record/research-projects/1204/risa-ipd-reducing-self-harm-in-adolescents-individual-patient-data-meta-analysis:

Schedule 2

Data to be supplied from the **Institution** to the **UoL** RISA-IPD research team is to facilitate an Individual Patient Data Meta-Analysis of existing randomised controlled trials of therapeutic interventions to reduce subsequent self-harm in adolescents. The project aims to identify subgroups of adolescents in whom therapeutic interventions for self-harm show some evidence of benefit (or dis-benefit). RISA-IPD is commissioned and funded by the UK National Institute of Health Research Health Technology Assessment program (project number 17/117/11), with ethical approval University of Leeds Reference: MREC 18-098

The **Institution** are asked to confirm they have permission to share participants' pseudonymised data, considering appropriate consent of participants or those with parental responsibility, and withdrawal of consent (as applicable).

The UoL RISA-IPD research team encourage discussion of any aspect of the data request, further details of which are below, with the study statistician and/or chief investigator prior to data transfer.

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1. De-identification and Pseudonymisation

We aim to reduce the burden for collaborating trialists as much as possible to facilitate the sharing of Individual Patient Data, however de-identification and pseudonymisation[1] of the dataset prior to data transfer is essential to retain anonymity of participants.

This requires removal of directly identifiable data:

- Name (full or partial) of participant, family member/s, therapists
- Address/postcode
- Name of treatment centre
- Telephone / email contact
- Date of birth
- NHS number or equivalent identifiers (i.e. hospital numbers)

Further de-identification of the dataset may be required depending on the format of the data held by collaborators (e.g. to remove sensitive free text terms); please discuss further de-identification with the UoL RISA-IPD research team if applicable. The UoL RISA-IPD research team undertake to check data on receipt (within a week where possible) to ensure data received are in accordance with data requested, and to check for missing, duplicated or identifiable data. If identifiable data are received, the UoL RISA-IPD research team will be obliged to delete the dataset/s containing identifiable data, and to re-request provision of de-identified and pseudonymised data.

Pseudonymisation[1]: *"The processing of personal data in such a way that the data can no longer be attributed to a specific data-subject without the use of additional information, provided that such additional information is kept separately and subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable person."*

[1]*Ohmann C, Banzi R, Canham S, et al. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. BMJ Open 2017;7:e018647. doi:10.1136/bmjopen-2017-018647*

2. Individual Patient Data Items

We recognise that trials will have collected data using a variety of formats, code lists and questions, and not all data items will be available from each trial. As such, data available may not correspond entirely to the data requested and we ask that equivalent data in the format available for your trial is provided. Similarly, if additional relevant trial data are available and not listed in the tables below, then please discuss this with the UoL RISA-IPD research team. The tables below therefore list the individual data items requested as a guide to the variables and domains sought. Data requested is at the participant level unless otherwise indicated.
To promote interoperability and retain meaning within interpretation and analysis, and to allow a full understanding of the data set, Individual Patient Data should as far as possible, be provided alongside:

- A basic data dictionary and study schedule describing the data provided
- Other relevant clinical trial data (e.g. protocols, original data collection forms, clinical study reports, statistical analysis plans)

Table 1 Baseline and randomisation data

Variable/s	Description
Trial ID	Unique pseudonymised trial identifier
Age	Age in years/months at randomisation
Gender	Male, Female
Ethnicity	e.g. White, Black, Asian, Other
LGBT status	e.g. identify as LGBT or not
Intellectual disability	e.g. Reading or writing difficulties, defined via IQ
Autistic Spectrum Disorder	e.g. Autism diagnosis: yes, no
History of abuse	e.g. parental abuse, sexual abuse, other
Looked after Children	e.g. living arrangements: with parents/guardians, foster care
Psychotropic medications	e.g. participant on prescribed medications for emotional and /or behavioural reasons: yes, no
Physical health	e.g. any physical health/disability problems
N previous self-harm events	As recorded for your trial.
Method of index self-harm event (*prior to study entry*)	e.g. self-poisoning, self-injury, etc.
Outcome of index self-harm event (*prior to study entry*)	e.g. no medical treatment, resulted in hospital attendance, admission
Comorbid psychiatric conditions	As measured using the scale used for your trial (See Table 2)
Centre Code / cluster identifier	Recruiting centre code / cluster (i.e. for cluster RCTs)
Randomisation design factors	e.g. stratification or minimisation factors
Randomised treatment allocation	Treatment A / Treatment B etc.
Date of randomisation	DD/MM/YYYY

Table 2 Questionnaire baseline and outcome data

Variable/s	Description
General psychopathology Depression Anxiety disorders Borderline personality disorder Eating disorders Unemotional/ Callous traits Suicidal ideation Quality of Life	**Questionnaire data** All self-reported, parent-reported, researcher-reported questionnaire data at all time points collected during the trial as measured within your trial. Specific domains of interest are specified, however we request data from all psychiatric, or other (ie QoL), questionnaires used within your trial
Timing of completion	e.g. Time point (baseline, 3 month, etc.), time relative to randomisation
Method of completion	e.g. postal, face to face, telephone
Completed by	e.g. young person, caregiver, researcher, therapist

Table 3 Treatment Data (all trial arms, Intervention and Control as applicable)

Variable/s	Description
Randomised treatment	
Randomised treatment allocation	Treatment A / Treatment B etc.
Treatment received according to protocol	e.g. Yes, No; if no , why not
Participant completed treatment	e.g. Yes, No patient withdrew, No patient did not attend
Number of sessions attended	
Length of sessions	
Duration of treatment (from randomisation)	e.g. Weeks, Months etc.
Time spent in treatment	e.g. Overall or at the session level; in minutes, hours
Fidelity / adherence to treatment	As recorded for your trial, fidelity may be at the therapist level
Other treatment receipt	e.g other relevant information: details of cross over, additional/alternative treatments received
Therapist details (participant level)	
Number of therapists associated with patients treatment	*e.g a single therapist, multiple therapists, N therapists*
Therapist ID	As recorded for your trial in pseudonymised coded format. Repeat as necessary for multiple therapists.
Main Therapist ID	e.g. Applicable when there were multiple therapists.
Therapist details (At study or therapist level as applicable**)**	
Therapist characteristics	e.g research therapist vs clinical therapist; consultant level:

	yes, no
Therapist supervision	e.g Any supervision (yes, no), level of supervision

Table 4 Clinical outcomes

Variable/s	Description
Details of self-harm events (including suicide attempts) at the patient level	
Length of follow-up for events	Timing relative to randomisation
Any events reported	Yes, No
Number of events	
Details of each recorded Self-Harm/suicide event at the patient level	
Method of reporting	e.g. Recorded from hospital medical records, self-reported (this may be at the event or trial level)
Timing of event	e.g. days, weeks or months post randomisation
Method of self-harm	e.g. self-poisoning, self-injury, etc.
Suicide attempt	e.g. Yes, No; if distinguished in your trial,
Outcome (administrative)	e.g. no medical treatment, resulted in hospital attendance (A&E/Admission)
Severity of event	If distinguished/collected and as reported in your trial.
Other clinical outcomes at the patient level	
Patient death	Yes / No
Timing of Death	e.g. weeks, months relative to randomisation
Cause of death	As recorded for your trial.

Table 5 Additional analysis data

Variable/s	Description
Any further variables used/with potential for use in trial analysis	To include data items used in primary and secondary outcome analysis not listed above. Including data used for missing data imputation, or for predicting whether outcome data are missing or not.

3. Data transfer process

Electronic data sets will be provided from the Institution to the UoL RISA-IPD research team in a suitable format that is recognised by a range of statistical software (e.g. SAS, SPSS, STATA). SAS is preferred, however the specific format will be in accord with the preference of the data provider.
Data will be sent to the UoL RISA-IPD research team via the Secure File Transfer service for the Clinical Trials Research Unit (https://lictr.leeds.ac.uk/sft/help/SFT_SendExt.html#/). The UoL RISA-IPD team member responsible for receipt and processing of data is the study statistician Alexandra Wright-Hughes.

4. Research Team Contact Details

Study Statistician
Alex Wright-Hughes, Senior Medical Statistician
CTRU, Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, LS2 9JT

Supervising Statistician
Rebecca Walwyn, Acting Associate Professor of Clinical Trials Methodology
Clinical Trials Research Unit, Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, LS2 9JT

Chief Investigator
Professor David Cottrell, Professor of Child & Adolescent Psychiatry
Leeds Institute of Health Sciences, University of Leeds, Leeds, LS2 9JT