Appendix 2

DATA ABSTRACTION FORM

**For any question with a free text response that does not apply, please enter "NA." For any question with a free text response whose answer is not specified, please enter "NS"**

Abstractor

- ◯ Johanna
- ◯ Sarah

**ELIGIBILITY CRITERIA**

Inclusion criteria (must meet all to be included)

- ☐ Is an informed consent intervention with a control group
- ☐ Has a quantitative, objective measure of patient comprehension as an outcome measure
- ☐ The consent is for a medical or surgical procedure
- ☐ The patients are consenting for themselves

Exclusion Criteria (if meets any, not to be included)

- ☐ Surrogate obtains consent
- ☐ Is an observational or cohort study
- ☐ Is explicitly described as a pilot or feasibility study or an exploratory trial
- ☐ Consent if for research
- ☐ Consent is for a screening test
- ☐ Consent is for an educational program
- ☐ Consent is for sharing of personal health information
- ☐ Consent is for an advanced directive
- ☐ Consent is for aid in dying
- ☐ Consent is for psychotherapy
- ☐ Consent is for prescription drug(s)
- ☐ Consent is for genetic testing
- ☐ Is a cancer consultation
- ☐ Is a contingency scenario

- [ ] Other
- [ ] None of the above

If "other" is selected, please specify

...

Study eligibility

- ◯ Yes
- ◯ No
- ◯ Maybe (need to discuss)

**Proceed only if study is confirmed to be eligible. Otherwise, stop here, save this record, and move on.**

**STUDY INFORMATION**

First author (last name, first initial)

...

Year published

...

Study type

- ◯ RCT
- ◯ NRCT

Procedure type

...

Study country

- ◯ USA
- ◯ Australia
- ◯ Austria
- ◯ Canada
- ◯ China
- ◯ England
- ◯ Finland

- ◯ France
- ◯ Germany
- ◯ India
- ◯ Ireland
- ◯ Italy
- ◯ Nepal
- ◯ New Zealand
- ◯ Nigeria
- ◯ Poland
- ◯ Scotland
- ◯ South Korea
- ◯ Switzerland
- ◯ Trinidad and Tobago
- ◯ Turkey
- ◯ Other

If ”other” is selected, please specify

...

Study setting: where the consent discussions took place

- ◯ Inpatient
- ◯ Outpatient clinic
- ◯ Not Specified
- ◯ Other

If ”other” is selected, please specify

...

Study setting: where the procedure was performed

- ◯ Inpatient
- ◯ Outpatient clinic
- ◯ Nursing home
- ◯ Not specified
- ◯ Other

If ”other” is selected, please specify

...

Inclusion criteria for study participants

...

Exclusion criteria for study participants

...

Intervention type (select all that apply)

- [ ] Written (e.g., consent form with additional information, information booklet or card)
- [ ] Audiovisial (non-interactive video, audio only, and visual aids)
- [ ] Extended discussion
- [ ] Test/feedback
- [ ] Computer based (e.g, electronic tablet application, interactive video or interface)
- [ ] Other

If "other" is selected, please specify

...

Short description of intervention

...

Number of study groups

- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ Other

If "other" is selected, please specify

...

Short description of control group informed consent process

...

Does the intervention require additional time with a health care provider?

- ◯ Yes
- ◯ No
- ◯ Unclear/not specified

If "yes" is selected, whose additional time does the intervention require? (physician, NP, RN, PA, health educator, etc.)

...

If "yes" is selected, how much additional time is required?

...

Study outcome measures (select all that apply)

- ☐ Patient comprehension
- ☐ Patient satisfaction
- ☐ Patient anxiety
- ☐ Provider satisfaction
- ☐ Length of consultation
- ☐ Other

If "other" is selected, please specify

...

Primary outcome

- ◯ Patient comprehension
- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Not specified
- ◯ Other

If "other" is selected, please specify

...

Timing of patient comprehension measure relative to procedure or surgery

- ◯ Before
- ◯ After
- ◯ Both before and after
- ◯ Not specified

Timing of patient comprehension measure relative to informed consent consultation (may check more than one)

- ☐ Immediately (within 1 hour)
- ☐ Within 24 hours (but >1 hour)
- ☐ Delayed (24 hours or more after consultation)
- ☐ Not specified

**STUDY RESULTS - for any result not specified, write NS**

Number of study participants (N)

...

Number of participants randomized to the control group

...

Number of participants randomized to the intervention

...

Age range of participants

...

Mean age of participants

...

Median age of participants

...

Percent female participants

...

Percent male patients

...

Percent of patients with other gender identification

...

Percent of patients who did not complete high school

...

Percent of patients with a high school education

...

Percent of patients with some college or trade school education

...

Percent of patients with some graduate education

...

Patient education specified in some other manner (please specify)

...

Percent of patients that are non-white

...

Percent of patients with low health literacy

...

Percent of patients with limited language proficiency (in the language in which the study was conducted)

...

Patient comprehension outcome - instrument/questionnaire type

...

Patient comprehension outcome - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified

Elements of patient comprehension assessed (select all that apply)

- ☐ Risks
- ☐ Benefits
- ☐ General knowledge about the procedure/surgery
- ☐ Alternatives to the procedure/surgery
- ☐ General knowledge about the medical condition
- ☐ Other
- ☐ Unclear

If "other" is selected, please specify

...

Patient comprehension outcome - difference in outcome measure (and standard deviation if reported)

...

Patient comprehension outcome - P value

...

Patient comprehension outcome - group favored

...

Other outcome 1

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 1 - if "other" is selected, please specify

...

Other outcome 1 - is the result statistically significant?

- Yes
- No
- Unclear or not specified
- NA

Other outcome 1 - is the instrument validated?

- Yes
- No
- Partially (adapted from a validated measure)
- Unclear or not specified
- No validated instrument required (e.g., lenght of consultation)
- NA

Other outcome 1 - group favored

...

Other outcome 2

- Patient satisfaction
- Patient anxiety
- Patient decisional conflict
- Provider satisfaction
- Length of consultation
- Other
- NA

Other outcome 2 - if "other" is selected, please specify

...

Other outcome 2 - is the result statistically significant?

- Yes
- No
- Unclear or not specified

- ◯ NA

Other outcome 2 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified
- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 2 - group favored

...

Other outcome 3

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 3 - if "other" is selected, please specify

...

Other outcome 3 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 3 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified

- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 3 - group favored

...

Other outcome 4

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 4 - if "other" is selected, please specify

...

Other outcome 4 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 4 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear ot not specified
- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 4 - group favored

...

Other outcome 5

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 5 - if "other" is selected, please specify

...

Other outcome 5 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 5 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified
- ◯ No validated instrument required (e.g., lenght of consultation)
- ◯ NA

Other outcome 5 - group favored

...

Other outcome 6

- ◯ Patient satisfaction

- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 6 - if "other" is selected, please specify

...

Other outcome 6 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 6 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified
- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 6 - group favored

...

Other outcome 7

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation

- ◯ Other
- ◯ NA

Other outcome 7 - if "other" is selected, please specify

...

Other outcome 7 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 7 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified
- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 7 - group favored

...

Other outcome 8

- ◯ Patient satisfaction
- ◯ Patient anxiety
- ◯ Patient decisional conflict
- ◯ Provider satisfaction
- ◯ Length of consultation
- ◯ Other
- ◯ NA

Other outcome 8 - if "other" is selected, please specify

...

Other outcome 8 - is the result statistically significant?

- ◯ Yes
- ◯ No
- ◯ Unclear or not specified
- ◯ NA

Other outcome 8 - is the instrument validated?

- ◯ Yes
- ◯ No
- ◯ Partially (adapted from a validated measure)
- ◯ Unclear or not specified
- ◯ No validated instrument required (e.g., length of consultation)
- ◯ NA

Other outcome 8 - group favored

...

**STUDY QUALITY REVIEW - Cochrange Risk of Bias 2 (RoB 2) Tool**

Study design

- ◯ Individually-randomized parallel-group trial
- ◯ Cluster -randomized parallel-group trial
- ◯ Individually randomized cross-over (or other matched) trial
- ◯ Non-randomized controlled trial
- ◯ Other
- ◯ Unclear

If "other" is selected, please specify

...

The review team's aim for this result is

- ◯ To assess the effect of assignment to intervention ('intention-to-treat' effect)

- ◯ To assess the effect of adhering to intervention (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (check all that apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ "Grey literature" (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

**RoB Domain 1: Risk of bias arising from the randomization process**

Randomization is employed

- ◯ Yes
- ◯ Partial or unclear
- ◯ No (if selected, skip Domain 1 questions)

1.1 Was the allocation sequence random?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

Risk-of-bias judgment domain 1

- ◯ Low
- ◯ High
- ◯ Some concerns
- ◯ Skip

**RoB Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)**

2.1 Were participants aware of their assigned intervention during the trial?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.2 Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.3 If "Yes," "Probably Yes," or "No Information" is selected for to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.4 If "Yes" or "Probably Yes" is selected for 2.3: Were these deviations from intended intervention balanced between groups?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.5 If "No," "Probably No," or "No Information" is selected for 2.4: Were these deviations likely to have affected the outcome?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

2.7 If "No," "Probably No," or "No Information" is selected for 2.6: Was there potential for a substantial impact (on the result) of the failure to analyze participants in the group to which they were randomized?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

Risk-of-bias judgment domain 2

- ◯ Low
- ◯ High

- ◯ Some concerns

**RoB Domain 3: Missing outcome data**

3.1 Were data for this outcome available for all, or nearly all, participants?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

3.2 If "No," "Probably No," or "No information" is selected for 3.1: Is there evidence that the result was not biased by missing outcome data?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No

3.3 If "No," or "Probably no" is selected for 3.2: Could missingness in the outcome depend on its true value?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

3.4 If "Yes," "Probably yes," or "No information" is selected for 3.3, do the proportions of missing outcome data differ between intervention groups?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

3.5 If "Yes," "Probably yes," or "No information" is selected for 3.3: Is it likely that missingness in the outcome depended on its true value?

- ◯ Not applicable

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

Risk-of-bias judgment domain 3

- ◯ Low
- ◯ High
- ◯ Some concerns

**RoB Domain 4: Risk of bias in measurement of the outcome**

4.1 Was the method of measuring the outcome inappropriate?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

4.3 If "No," "Probably No," or "No information" is selected for 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

4.4 If "Yes," "Probably yes," or "No information" is selected for 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

4.5 If "Yes," "Probably yes," or "No information" is selected for 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

- ◯ Not applicable
- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

Risk-of-bias judgment domain 4

- ◯ Low
- ◯ High
- ◯ Some concerns

**RoB Domain 5: Risk of bias in selection of the reported result**

5.1 Was the trial analyzed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No

- ◯ No information

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

- ◯ Yes
- ◯ Probably yes
- ◯ Probably no
- ◯ No
- ◯ No information

Risk-of-bias judgment domain 5

- ◯ Low
- ◯ High
- ◯ Some concerns

Any additional notes or issues with the form (please reference specific question/data point)

...