Ethics ETH2526-1074: Prof Katerina Hilari (Medium risk)

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Category	Academic Staff
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Project	Measure for Dyadic Conversation in Aphasia (MDCA): Psychometric testing
School	School of Health & Medical Sciences
Department	Allied Health
Current status	Approved after amendments made

Ethics application

Risks

R1) Does the project have funding?
No

R2) Does the project involve human participants?
Yes

R3) Will the researcher be located outside of the UK during the conduct of the research?
No

R4) Will any part of the project be carried out under the auspices of an external organisation, involve collaboration between institutions, or involve data collection at an external organisation?
Yes

R5) Does your project involve access to, or use of, terrorist or extremist material that could be classified as security sensitive?
No

R6) Does the project involve the use of live animals?
No

R7) Does the project involve the use of animal tissue?
No

R8) Does the project involve accessing obscene materials?
No

R9) Does the project involve access to confidential business data (e.g. commercially sensitive data, trade secrets, minutes of internal meetings)?
No

R10) Does the project involve access to personal data (e.g. personnel or student records) not in the public domain?
No

R11) Does the project involve deviation from standard or routine clinical practice, outside of current guidelines?
No

R12) Will the project involve the potential for adverse impact on employment, social or financial standing?
No

R13) Will the project involve the potential for psychological distress, anxiety, humiliation or pain greater than that of normal life for the participant?
No

R14) Will the project be conducted or supported by any U.S. federal department or agency?
No

R15) Will the project involve research into illegal or criminal activity where there is a risk that the researcher will be placed in physical danger or in legal jeopardy?
No

R16) Will the project specifically recruit individuals who may be involved in illegal or criminal activity?
No

R17) Will the project involve engaging individuals who may be involved in terrorism, radicalisation, extremism or violent activity and other activity that falls within the Counter-Terrorism and Security Act (2015)?
No

Applicant & research team

T1) Principal Applicant

Name

Prof Katerina Hilari

Provide a summary of the researcher's training and experience that is relevant to this research project.

Professor Hilari is an aphasia expert SLT researcher. She is an expert on outcome measurement for people with aphasia. She has led multiple aphasia projects, including psychometric studies, and has supervised multiple students in their research.

T2) Co-Applicant(s) at City

Name

Prof Madeline Cruice

Provide a summary of the researcher's training and experience that is relevant to this research project.

Professor Cruice is an aphasia expert SLT researcher. She co-leads the APT research project (see below) that this project is contributing to. She has led multiple aphasia projects and has supervised multiple students in their research.

Name

Dr Sally McVicker

Provide a summary of the researcher's training and experience that is relevant to this research project.

Dr McVicker is an aphasia expert SLT clinician, and experienced practice educator and aphasia researcher. She leads Aphasia ReConnect a charity for people with aphasia that will assist with recruitment and data collection.

Name

Dr Abi Roper

Provide a summary of the researcher's training and experience that is relevant to this research project.

Dr Abi Roper is an aphasia expert SLT clinician, and computer scientist. She has led many aphasia projects with tech applications. She will assist with tech aspects of the project and online data forms for data collection.

T3) External Co-Applicant(s)

T5) Do any of the investigators have direct personal involvement in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?
No

T6) Will any of the investigators receive any personal benefits or incentives, including payment above normal salary, from undertaking the research or from the results of the research above those normally associated with scholarly activity?
No

T7) List anyone else involved in the project.
This project is an add-on project to an NIHR PGfAR funded project: the Aphasia Partnership Training (APT) project. APT is co-led by Professor Madeline Cruice at City St George's and Professor Rebecca Palmer at the University of Sheffield.

Dr Sharon Adjei-Nicol and Natascha Ullrich are experienced SLTs, members of the APT team and will assist with data collection.

Dr Annette Rotherham is the developer of the MDCA. She will assist with the interpretation of the data.

Dr Silia Vitoratou, from Kings College London is a Psychometric statistician and will oversee the data analysis of this project.

Dr Sally McVicker, as well as a staff member at City St George's, leads Aphasia ReConnect, a charity for people with aphasia. Aphasia ReConnect has agreed to support this project with recruitment and data collection (City St George's SLT students in placement) as the MDCA is an interesting outcome for their services.

We also plan to supervise student projects within this study. We will also invite student volunteers who wish to increase their experience with people with aphasia to collect data for this project. These student names will be added on to the application through amendments once confirmed.

Project details

P1) Project title
Measure for Dyadic Conversation in Aphasia (MDCA): Psychometric testing

P1.1) Short project title
MDCA - Psychometrics

P2) Provide a lay summary of the background and aims of the research, including the research questions (max 400 words).
BACKGROUND:

Communication partner training (CPT) is an intervention for people with aphasia and their partners that aims to improve the communication skills of both partners, in order to improve their conversations. One CPT programme developed by our team (led by Professor Madeline Cruice from City St George's and Professor Rebecca Palmer from University of Sheffield) is Aphasia Partnership Training (APT). We have previous and continuous work with APT and we need appropriate outcome measures to measure the intended outcomes of APT.

NEED FOR THE STUDY:

Available outcome measures for communication typically look at the skills of just the person with aphasia. Very few measures exist that capture the communication skills of both partners (dyadic communication), which is the key intended outcome of CPT and APT. In our previous work, we have evaluated the psychometric properties of existing measures and they are limited (publication pending).

THE CURRENT STUDY'S AIM:

A new measure has been recently developed called Measure of Dyadic Conversation in Aphasia (MDCA). MDCA has been developed following COSMIN guidelines for patient reported outcome measures and has very good content validity (Rotherham, 2025 PhD thesis available https://espace.library.uq.edu.au/view/UQ:a647829). This project aims to begin the process of testing the psychometric properties of MDCA.

RESEARCH QUESTIONS:

Specifically the following research questions will be addressed;

1) What is the reliability (internal consistency; stability)of MDCA with community dwelling people with stroke and aphasia and their primary communication partners.

2) What is the construct validity of MDCA with community dwelling people with stroke and aphasia and their primary communication partners.

3) What is the relationship (correlation) of the PWA (MDCA-A) and communication partner (MDCA-P) versions of MDCA

P4) Provide a summary and brief explanation of the research design, method, and data analysis.

DESIGN:

The study will be an interview-based, cross-sectional, psychometric study.

PROCEDURE AND METHOD:

Potential participants will have initial information about the project through an ad or information from their referring group facilitator or clinician. Those expressing an interest to take part will be given the participant information sheet and will be seen by a project researcher. They will be seen at a location of their choice (e.g., online or at home or a community setting) and the researcher will give them full information about the project and check their eligibility to take part. Those with aphasia will also complete a screening test (Frenchay Aphasia Screening Test, FAST short version) to ensure they have adequate comprehension to understand what the study entails. Verbal and/or written consent will be obtained. This first visit will take about 45min and no more than 1 hour.

Those expressing an interest to take part will be visited a second time. Consent will be confirmed at this visit. Participants will then complete the MDCA and a selection of other outcome measures to capture the intended outcomes of APT (Palmer et al., 2025). These will comprise communication (the Communicative Participation Item Bank, CPIB for PWA; the Communicative Effectiveness Index, CETI, for Partners), thoughts and feelings (the General Health Questionnaire, GHQ-12; Stroke and Aphasia Quality of Life scale, SAQOL-39g PWA). The researcher will also complete the Therapy Outcome Measures for Aphasia (TOMs). Participants will also be briefly asked about what they thought of the MDCA and how well communication measures used captured their communication

with their partner. Testing with participants with aphasia is anticipated to take about 1 hour, 1hr 15min (short case history form, FAST, MDCA-A, CPIB, GHQ-12, SAQOL-39g); and less than 1 hour (30-40min) with communication partners (short case history form, MDCA-P, GHQ-12, CETI). Participants will then be seen one more time to complete the MDCA again for test-retest reliability purposes (~20min).

DATA ANALYSIS:

Descriptive statistics will be used to describe participant characteristics and their performance/ scores on the measures used. Missing data (%) will inform acceptability. Internal consistency indices will comprise Cronbach's alpha, alpha if item deleted, item-total and inter-item correlations. Correlation statistics will be used for construct validity, and relationship between MDCA-A and MDCA-P testing. We anticipate moderate to high correlations between MDCA communication items and CPIB, CETI, TOMs activity and participation, SAQOL-39g, and GHQ-12. Moderate correlations are anticipated between MDCA relationship items and GHQ-12 and SAQOL39 psychosocial domain. Lower correlations are expected between MDCA and FAST, SAQOL-39 physical, and TOMs impairment. For test re-test reliability, suitable measures of agreement will be used on item and total score level based on the distribution properties of the variables involved (Psi coefficient for ordinal and skewed data, and Intraclass Correlation Coefficient for symmetrical data, for instance). Established guidelines will be followed for interpretation.

P4.1) If relevant, please upload your research protocol.

P5) What do you consider are the ethical issues associated with conducting this research and how do you propose to address them?

The project is low risk as it involves assessing people with aphasia and their communication partners on established measures of language, communication, and feelings, and a new measure developedd through co-design with them. There still remain ethical considerations.

INFORMED CONSENT. For all participants clear information will be provided to ensure they understand what the project entails. Information will highlight that participation is entirely voluntary. In addition for those with aphasia, an experienced speech and language therapist researcher (SLT) or SLT student trained in communicating with people with aphasia will provide information on the project and check participant's understanding of information provided and willingness to take part. To support informed consent for those with aphasia:

o Participant Information (PIS) will be provided in an aphasia accessible format

o A minimum comprehension criterion on the FAST at screening will be used (=/>7 on receptive domains).

CONFIDENTIALITY. Data must be kept confidential and stored securely. To this end:

o Data about participants will be stored securely on the encrypted, password protected City St George's University of London OneDrive.

o Participants consent to any data collection

o Identifying information (consent forms) kept separately to study data.

DISTRESS AND BURDEN. Participants must not be over burdened.

o The participants with aphasia' diagnoses and symptoms may already be stressful and emotional. It will be clear that study participation is voluntary, and participants can withdraw at any time without giving a reason. This will be explained to them.

o Sometimes completing assessments (language, feelings, relationships) can be upsetting for people with aphasia as it highlights their disability. Researchers will offer breaks, time to talk, and can reschedule. Researchers will be trained to share information for further services when these are indicated e.g., local support groups, a GP referral for psychological support

o Testing sessions will be time limited. Participants will be offered regular breaks and refreshments as needed. If a participant appears tired they will be given the option of an alternative/additional session.

P6) Project start date
The start date will be the date of approval.

P7) Anticipated project end date
30 Jun 2027

P8) Where will the research take place?
Sessions will take place either online or at a location of participants's choice, e.g. their home, a stroke and aphasia community group meeting place, a quiet place in their locality.

P10) Is this application or any part of this research project being submitted to another ethics committee, or has it previously been submitted to an ethics committee?
No

External organisations

E1) Provide details of the external organisation/institution involved with this project.
Aphasia ReConnect, a charity for people with aphasia, is a partner in this project. They are interested in the MDCA as an outcome measure for their services and are keen to collaborate in the testing of the measure. They will support the project through referring participants and collecting data. The collaborating clinician at Aphasia ReConnect is a City St George's staff member and has City SLT students on placement. These students get experience with measuring outcomes with people with aphasia as part of their placement and can collect data with the proposed measures for this study.

The University of Sheffield. Data will also be collected in and around Sheffield through members of the APT research team at that location (listed in this application (Natascha Ullrich)). Sheffield Aphasia Centre takes Sheffield SLT students on placement and they are happy to collect data for the project. Following City St George's ethics review, additional approval will be sought from University of Sheffield.

E2) If applicable, has permission to conduct research in, at or through another institution or organisation been obtained?
Yes

E2.1) Provide details and attach the correspondence.

Following City St George's ethics review, the University of Sheffield will follow their process for permission for data collection at that site.

Human participants: information and participation

The options for the following question are one or more of:
'Under 18'; 'Adults at risk'; 'Individuals aged 16 and over potentially without the capacity to consent'; 'None of the above'.

H1) Will persons from any of the following groups be participating in the project?
None of the above

H2) How many participants will be recruited?
200

H3) Explain how the sample size has been determined.
Our expert psychometrics statistician Dr Silia Vitoratou Psychometrics and Measurement Lab, Biostatistics and Health informatics, IoPPN, King's College London, who is a collaborator on the project, has calculated power, and advised on data analysis.

Psychometric studies require large samples. We will aim for 100 PWA and as many partners as we can recruit and no more than 100. For each of the subgroups, with 100 individuals, 80% power is achieved in detecting modest agreement according to ICC=0.8 (power calculated at alpha=0.05 using the ICC package in R).(1) This sample results to power >0.80 for internal consistency analysis with alpha levels close to 0.80.(2)

References:

1. Zou GY. Sample size formulas for estimating ICC with precision and assurance. Stat Med. 2012;31:3972-3981.

2. Heo M, et al. Statistical power as a function of Cronbach alpha of instrument questionnaire items. BMC Medical Research Methodology. 2015:86.

H4) What is the age group of the participants?

Lower	Upper
18	

H5) Please specify inclusion and exclusion criteria.
Information on criteria below will be collected from participants through a case history form and also, for those referred to the study, from the referring source (e.g., SLT, group co-ordinator).

PARTICIPANTS WITH APHASIA:

Inclusion criteria: aged 18+ years; aphasia subsequent to stroke(s) at least 3 month prior to consent; score >/= 7 on receptive domains of FAST to ensure capacity to consent. Optional: able to identify a regular communication partner who is willing to take part in the study too.

Exclusion criteria: have another speech and language disorder caused by a neurological deficit other than stroke; still in an acute hospital; have uncorrected visual or hearing problems; have a cognitive difficulty that is considered to limit their ability to respond reliably to questionnaires; have other severe or potentially terminal comorbidity on grounds of frailty.

COMMUNICATION PARTNERS

Inclusion criteria: aged 18+ years; communication partner for the consenting PWA; communicate with the PWA at least 3 times a week.

Exclusion criteria: have uncorrected visual or hearing problems; have a cognitive difficulty that is considered to limit their ability to respond reliably to questionnaires; have severe or potentially terminal comorbidity on grounds of frailty.

H6) What are the potential risks and burdens for research participants and how will you minimise them?

The project is very low risk as it involves assessing people with aphasia on established measures of communication, wellbeing/mood and quality of life. It is possible that some questions in these assessments may upset a participant. The researchers will be aphasia-expert SLTs, or SLT students supervised by aphasia expert SLTs, with skills to support participants. The assessment will be paused or stopped and resumed at another time and the issue discussed.

It is also possible that the wellbeing measure may identify that participants suffer from high emotional distress/depression. On such occasions this finding will be discussed with the participant and a course of action will be agreed. Support will be provided to implement this plan. This may involve raising this finding (with their consent) or encouraging them to raise this with their referring clinician (if applicable) and/or seek support with GP. It may involve supporting them to make contact and complete e-health consultation requests. Where appropriate, we may recommend and help participants to contact support organisations such as the Stroke Association, Aphasia Re-Connect or other local groups.

Potential burdens include time and travel. In terms of the time requirements of the project, it will be clearly included in the participant information sheet and it will be explained to participants what the time commitment is, for them to make an informed decision. Breaks will be offered as appropriate or the opportunity to continue the assessment at another time. Participants also have the right to withdraw at any time. In terms of travel, participants will be offered the option to be seen at a location of their choice (at home, online, or settings that will require travel such as a community setting, a community group meeting place, the University). It will be their choice. If they choose to be seen in a community group meeting place, we will aim to visit them on a day they visit their group anyway to minimise additional travel. Any travel expenses incurred for participation to this project will be re-imbursed (PI's discretionary account).

H7) Will you specifically recruit pregnant women, women in labour, or women who have had a recent stillbirth or miscarriage (within the last 12 months)?

No

H8) Will you directly recruit any staff and/or students at City?

Students

None of the above

H8.1) If you intend to contact staff/students directly for recruitment purpose, please upload a letter of approval from the respective School(s)/Department(s).

H8.2) Will you recruit students by virtue of their attendance on specific programmes or modules?

No

H9) How are participants to be identified, approached and recruited, and by whom?

We will advertise the project on social media, to third-sector organisations and people known to the broader APT project and the University who have given permission to be contacted for research. We will share information with local aphasia support groups, provide project information and answer any questions. Initial eligibility (adult, aphasia due to stroke, >3m post onset) will be checked by group facilitators or project researchers.

If someone is interested in taking part, they will receive the participant information sheet. They will then have a session with a project researcher (SLT or SLT student). They will be given full information on the project and answer questions. Researchers will check criteria based on participant self-report and information from carers/partners, and those with aphasia will be screened with the FAST. Consent will be obtained (verbal and/ or written). Consent will be confirmed in the first data collection visit approximately 1 week later (at least 3 days later).

H10) Please upload your participant information sheets and consent form, or if they are online (e.g. on Qualtrics) paste the link below.

H11) If appropriate, please upload a copy of the advertisement, including recruitment emails, flyers or letter.

H12) Describe the procedure that will be used when seeking and obtaining consent, including when consent will be obtained.

No one without capacity to consent will be included in the study. As indicated in sections P4 and P5, processes will be in place to ensure capacity to consent, including the following: those with aphasia will complete a screening test (Frenchay Aphasia Screening Test, FAST short version) to ensure they have adequate comprehension to understand what the study entails and provide consent. In terms of process:

a) A member of the research team (including student SLTs trained in communication with people with aphasia and consent processes) will complete the screening assessment (The Frenchay Aphasia Screening Test, 10mins) and check inclusion criteria. If they meet criteria the researcher will go through the PIS and answer any questions they have about the project. Then they will be asked if they would like to take part. If they would, they will be invited to complete the consent form.

b) A copy will be kept for researchers file and a copy will be left with the participant (emailed if consent completed online).

c) The PIS was given when interest was first expressed (see H9)

d) At least 3 days

H13) Are there any pressures that may make it difficult for participants to refuse to take part in the project?

No

H14) Is any part of the research being conducted with participants outside the UK?

No

Human participants: method

The options for the following question are one or more of:
'Invasive procedures (for example medical or surgical)'; 'Intrusive procedures (for example psychological or social)'; 'Potentially harmful procedures of any kind'; 'Drugs, placebos, or other substances administered to participants'; 'None of the above'.

M1) Will any of the following methods be involved in the project:
None of the above

M2) Does the project involve any deceptive research practices?
No

M3) Is there a possibility for over-research of participants?
Yes

M3.1) What steps will be taken to safeguard the participants from over-research?
We will ask potential participants if they are involved in any other research projects and if they are feeling overburdened. People approached are under no obligation to take part in the research and this will be made clear. People with aphasia report feelings of isolation following the stroke and value the opportunity for both altruism and/or social contact that comes with being involved in research.

M4) Please upload copies of any questionnaires, topic guides for interviews or focus groups, or equivalent research materials.
M5) Will participants be provided with the findings or outcomes of the project?
Yes

M5.1) Explain how this information will be provided.
Participants can request that their assessment scores are shared with them. We will not share results directly with participants as will not keep their contact details.

At the end of the project, we will share results about the study on our City Access Resources for Aphasia website, through publications read by users (e.g. Aphasia ReConnect newsletter, Stroke Association newsletters) and social media.

M6) If the research is intended to benefit the participants, third parties or the local community, please give details.
The research will not benefit the participants directly. However, it will generate evidence on outcome measures (MDCA-A and MDCA-P) that are needed in clinical practice and research with people with aphasia.

M7) Are you offering any incentives for participating?
No

M8) Does the research involve clinical trial or clinical intervention testing that does not require Health Research Authority or MHRA approval?
No

M9) Will the project involve the collection of human tissue or other biological samples that does not fall under the Human Tissue Act (2004) that does not require Health Research Authority Research Ethics Service approval?
No

M10) Will the project involve potentially sensitive topics, such as participants' sexual behaviour, their legal or political behaviour, their experience of violence?
No

M11) Will the project involve activities that may lead to 'labelling' either by the researcher (e.g. categorisation) or by the participant (e.g. 'I'm stupid', 'I'm not normal')?
No

Data

D1) Indicate which of the following you will be using to collect your data.
Questionnaire
Computer-based tasks, screen recording or software instrumentation

D2) How will the the privacy of the participants be protected?
Anonymised sample or data

D3) Will the research involve use of direct quotes?
No

D5) Where/how do you intend to store your data?
Data to be kept in a locked filing cabinet
Password protected computer files
Storage at City
Storage at other site

D5.1) If stored at another site, please provide details.
Some data will not be collected by City St George's researchers. We have minimised the need to store data at another site in the following ways. We have Qualtrics forms to support data collection in this project for consent forms, case history information, CPIB, GHQ-12, SAQOL-39. Researchers can enter data directly to City St George's Qualtrics forms during data collection for these measures.

We plan to create similar Qualtrics forms for the remaining measures (MDCA-A, MDCA-P, CETI, experience questions). In the meantime and also as back up when devices may not be available, hard copy data may also be collected. These will be stored in locked filling cabinets. Researchers collecting data will be given access to a City St George's One Drive folder to upload scanned forms,

as soon as possible after data collection. Once forms are uploaded, hard copies and scans will be destroyed.

Each person or group of persons from one setting (e.g., Sheffield, Aphasia ReConnect) will have access to their unique folder so that they cannot access other participants data. This folder will regularly be emptied with data transferred to the City St George's research team's OneDrive folder for storage and analysis.

D6) Will personal data collected be shared with other organisations?
Yes

D6.1) Will the other organisation be a joint data controller with City or a data processor on behalf of City?
Data processor

D6.2) Detail the scope of any data sharing requirements (joint data controller) or data processing contract (data processor on behalf of City) with the other organisation.
Anonymised dataset from the project will be shared with the project statistician who is based at Kings College London. This will be outlined in a data processing agreement.

D7) Will the data be accessed by people other than the named researcher, supervisors or examiners?
Yes

D7.1) Explain by whom and for what purposes.
We aim to offer this project as a student project to SLT students in pre-reg and post-reg programmes. These students working under our supervision will be named /added to the application when known and they will be DBS checked speech and language therapy students.

D8) Is the data intended or required (e.g. by funding body) to be published for reuse or to be shared as part of longitudinal research or a different/wider research project now or in the future?
Yes

D9) Does the funding body or your professional organisation/affiliation place obligations or recommendations on the retention and destruction of research data?
Yes

D9.1) What are your affiliations/funding and what are the requirements?
City St George's is the affiliation. Psychometric studies require large data sets for further analyses (e.g. ~300 for factor analysis). We may be involved in further projects testing the psychometrics of MDCA. It will be specified in the PIS and CF that anonymised data may be shared with other researchers for future research and explicit consent will be sought.

D10) How long are you intending to keep the research data generated by the study?
As per University guidelines 10 years.

D11) How long will personal data be stored or accessed after the study has ended?
10 years

D12) How are you intending to destroy the personal data after this period?
All stored data will be digital data that will be deleted from the City University OneDrive and computer bin will be emptied.

Health & safety

HS1) Are there any health and safety risks to the researchers over and above that of their normal working life?
Yes

HS2) How have you addressed the health and safety concerns of the researchers and any other people impacted by this project?
It is anticipated that most visits will be online or public space, e.g. University clinic, a community group setting. Researchers will also go on home visits. Home visits are part of a researcher's and a clinician's normal working life. Researchers will follow City St George's University of London's lone worker policy to mitigate any potential risks e.g., calendars are shared so team members know where they are, they will text a colleague on arrival and when leaving. The researchers on the team are experienced clinicians or SLT students under their supervision and therefore have the experience to assess possible risk and take appropriate action.

HS3) Are there hazards associated with undertaking this project where a formal risk assessment would be required?
No