



Project Summary

Easy Text

Including adults with capacity
and communication difficulties
in research



Including adults with capacity and communication difficulties in ethically-sound research

Written by:

Karen Bunning
Rob Heywood
Anne Killeff
Peter E. Langdon
Ciara Shiggins

With:

Oluseyi Jimoh
Hayley Ryan
Marcus Redley
Yvonne Plenderleith



Acknowledgements

The Nuffield Foundation

The authors wish to acknowledge the support of the Nuffield Foundation in funding our project, providing support at every stage of the funded period, and offering flexibility in terms of project completion during a pandemic. On this latter point, we would like to express our particular gratitude to Catherine Dennison for her invaluable support, and her willingness to listen and to consider alternatives.

The Nuffield Foundation is an independent charitable trust with a mission to advance social well-being. It funds research that informs social policy, primarily in Education, Welfare, and Justice. It also funds student programmes that provide opportunities for young people to develop skills in quantitative and scientific methods. The Nuffield Foundation is the founder and co-funder of the Nuffield Council on Bioethics, and the Ada Lovelace Institute, and sole funder of the Nuffield Family Justice Observatory. The Foundation has funded this project, but the views expressed are those of the authors and not necessarily the Foundation. Visit www.nuffieldfoundation.org.



This **project** was **funded by** the **Nuffield Foundation**.

Advisory Group

We would like to **thank members of the Advisory Group**. You provided **help** from the **beginning** of the **project**. Your **support helped us** to **make** the **research suitable** and **easy to understand** for everyone.

Working Group

We would like to **thank members of the Advisory Group**. You **helped** us by sharing your **experience**. You **helped** us to **make documents** that was **suitable** and **easy to understand** for **those living with capacity and communication difficulties**.

Art Group

We would also like to **thank members of the Art Group**.

You helped us by making **drawing and pictures** for **Project ASSENT**.

Administrative Support

Thanks to Emma L. Jones who helped with the **day to day running** throughout the project.

Health Research Authority

Our **gratitude** for their **help in data collection** in **Stage 2** of the project.

Construction of Reusable Learning Object

Thanks to **Marshall E-Learning Consultancy** for helping to **make the e-guidance**.

Our Participants

Finally, thanks to all **our participants** who **shared their thoughts and ideas** with us during the **project**.

The **date** of this **Report** is **1st October 2021**

There are **words** in this document that **may be difficult** for you. **We have put these words in red**. These **words** are **explained** in the **glossary** below:

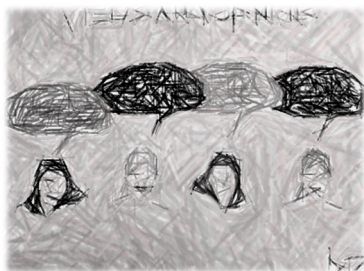
Glossary

Capacity	<i>Able to make own decision</i>
Lack capacity	<i>Not able to make own decision</i>
Consent	<i>To agree to take part in research</i>
Ethical	<i>If something is right or wrong</i>
Mental capacity act	<i>These are the rules that say how people with capacity difficulties must be treated in research</i>
Code of practice	<i>A document that goes with the Mental Capacity Act. It gives extra help on how research can take place.</i>
Include	<i>Allowed to be part</i>
Exclude	<i>Not allowed to take part</i>
Inclusion	<i>A way of allowing someone to take part in research.</i>
Consultee	<i>Someone who knows the person well and can advise the researcher how they feel about taking part in research.</i>
Health Research Authority	<i>A group established by the government that promote safe research</i>

Ethics committee	These are teams who read research proposals and say whether it is safe and sound or not.
Research ethics committee	These are teams who read research proposals and say whether it is safe and sound or not.
Inclusion in research	When a person is allowed to take part in research.
Media	The way information is passed on or given
Capacity & Decision-making	To be able to understand and decide what to do.
Participant Information Sheets	A document that is used to explain what a research is about. it also tells what people need to do if they want to take part in the research.
Assent	To show agreement
Dissent	To show disagreement
Retrospective survey	Research carried out using information on events that have taken place in the past
Hansard reports	A record of exactly what is said in parliament
Activities & participation	Research about what a person can do

Body function & structure	Research about parts of the body and what the part does
Environment	Research about what surrounds a person and where they live
Intervention	Research about how things change after a new way of doing things is introduced.
Altruism	Caring for other people without concern for yourself
Gatekeepers	A gatekeeper acts as the go between a researcher and someone who is invited to take part in research. a gatekeeper can allow or disallow the researcher to contact people.
Adaptations	Changes in the way things are done to allow others to fit in.
Accommodations	A way of changing what is done and how it is done to fit in with what people need.
Working Group	People meeting together to develop materials to be used in the project.
Reusable Learning Object	Documents that is available online from which people can learn.
Law and ethics	The law and safe research

<i>Intrusive research</i>	<i>Research that can only happen if a person agrees to take part</i>
<i>Autonomous decisions</i>	<i>When a person is able to make their own decision</i>



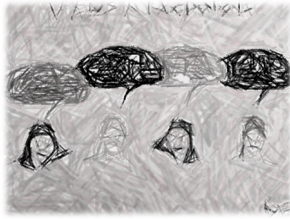
Project Summary

This is the **summary report** of **Project ASSENT**. A project about **including adults with capacity and communication difficulties** safely in **research** carried out in **England and Wales**. The project lasted **three years**. It began in **2018** and ended in **2021**.

In this **summary report** you will **read about**:

- Why we carried out Project ASSENT
- What we did
- How it was done
- What we found out
- What the findings mean
- What should happen next.

The **full report** is available on our project website:
<https://www.uea.ac.uk/groups-and-centres/assent/documents>



Overview of Project

Obtaining **consent** is key to involving human participants in research. It shows **respect for people's right to make their own decisions**. It also shows that the person has **understood the information** they were **given**, and made their **decision** on that basis. In our society, there are many **people living with capacity and communication difficulties**. These are people who may find it **difficult to make some or all their decisions** or **express their decision**.

This includes people living with:

- **autism**
- **intellectual disabilities**
- **aphasia after stroke**
- **brain injury**
- **mental health difficulties**
- **dementia.**

The number of **people living with capacity and communication difficulties** is increasing. **Better healthcare** is one **reason** for this.

There are **ethical questions** about **if it is okay to include** people with **capacity and communication difficulties** in **research**. Many people with these difficulties are **left out by researchers** and **ethics committees**.

Researchers and ethics committees may **think** it is **safer to leave them out** for their own protection.

When **people with capacity and communication difficulties** are **not included in research**, **healthcare services** may **not be suitable** for them.

Project ASSENT aimed to **find better ways for researchers to include** people with **capacity and communication difficulties** safely in **research**.



Methods, Approaches & Activities

Project ASSENT had **three (3) stages**:

1. The law and ethics in research
2. How research is currently being done
3. Developing guidance to help researchers to include adults with **capacity and communication difficulties** in research

We used **many different methods** to carry out the **project**.



Stage 1. The law and **ethics** in research

We looked at the **laws and guidelines** to do with **capacity** and **consent** in **England and Wales**. We looked at the **Mental Capacity Act** (MCA, 2005) and the **Code of Practice** (CoP, 2007). The **Code of Practice** is a document that goes with the **Mental Capacity Act**.

We looked at **three sources** of **information**:

1.1 The Law

We **reviewed different documents** that discussed the law **and recommendations** about **those who lack capacity**.

We looked at:

- the **Mental Capacity Act 2005** (the law).

- the **Hansard reports** which talk about **debates** people had **before the law** was put into effect.
- **legal cases**

1.2 Policy Guidance

We first looked at what was said about **carrying out research safely** in the **Code of Practice**.

The **Health Research Authority (HRA)** exist to **promotes safe research**. We looked at the **advice** given by the **Health Research Authority (HRA)** on **their website** about carrying our **research safely**.

We **counted words** and **topics** that were relevant to **adults with capacity and communication difficulties** in the **documents**.

1.3 How these laws and guidelines have been used by researchers.

We looked at **research** involving **adults with capacity and communication difficulties**. We looked at research from **when** the **Mental Capacity Act** (the law) started **being used**.



Stage 2. How research is currently being done

We looked at how **research that includes adults with capacity and communication difficulties** is **currently being done safely** in **England and Wales**.

We used **four sources** of **information**:

2.1 How research is reviewed by **ethics committees** in **England and Wales**.

In this part of **project ASSENT**, we first looked at **research from the past**.

The **Mental Capacity Act** started being used in **2007**. We looked at **research** that took place **since** the **Mental Capacity Act** started being used in **2007**.

This was done by **looking at** the **health research website** (<http://www.hra.nhs.uk/news/research-summaries/>).

We then **looked at research** that was **planned**. This was done by **checking out** the **applications** made to **Research Ethics Committees (REC)** in **England**. **Applications** made over a **12-month period**, from **September 2018** to **August 2019**.

2.2 How materials and resources have been adapted for participant recruitment.

In this part of **Project ASSENT**, we looked at how **materials and resources** have been **adapted** when asking **people with capacity and communication difficulties** to take part in research.

We did this by **looking at** how these **materials and resources** were **designed** and what was **included** in them.

2.3 How do researchers make decisions

In this part of **Project ASSENT**, we were **interested in** how researchers make **decisions** about whether to **include** or **exclude** **people with capacity and communication difficulties** in research.

We did this by asking **researchers** questions using a online **questionnaire**.

2.4 Views and opinions of groups interested in inclusion

We carried out **interviews** with **different groups** who would be **interested in** the **inclusion** of **adults with capacity and communication difficulties in research**. They are:

- 1. Members of research ethics committees;**
- 2. Researchers;**
- 3. Healthcare professionals as well as people who support or care for people with;**
- 4. Adults with capacity and communication difficulties.**

Adults with **capacity and communication difficulties** were those with:

- **autism**
- **intellectual disabilities**
- **aphasia after stroke**
- **brain injury**
- **mental health difficulties and**
- **dementia.**



Stage 3. Developing guidance to help researchers to include adults with capacity and communication difficulties in research

In this **part** of the **project**, we developed **guidance** to **support researchers** to **include adults with capacity and communication difficulties** in research.

3.1 Bringing together findings from Part 1 and Part 2.

In the **first part of this stage**, we brought **findings** from **part 1 and 2** of the project together. We **looked at** all the **findings** to see what **things** were **similar or different**.

3.2 Development of evidence-based guidance.

The **second part of this stage** of the project was to **develop guidance** to support **including adults with capacity and communication difficulties**.

This **guidance** was **made** by **organising** the **key messages** from **our findings** from **part 1** and **part 2** of the project. We used our findings to develop **practical information** and **guidance**. The **guidance** will be available **online**.

3.3 Asking people what they think of the guidance

We asked **researchers**, **ethics committee** members and **people who ask for research to be done** to try out the **guidance** that we made to support including **adults with capacity and communication difficulties** in **research**.

After they **tried out** the **guidance**, we asked them to fill out a **questionnaire** to tell us **what they thought** about the **guidance**.



Summary of findings

Part of the research	What we did	What was looked at	
1. The law and ethics in research	1.1 Review of MCA (2005)	Primary sources	31
		Secondary sources	54
	1.2 Review of CoP (2007) & policy guidance	Policy guidance documents	14
		CoP	1
	1.3 Systematic review of the literature	Full text review	134
		Final sample	29
2. How research is currently being done	2.1 Survey of REC review of research applications	Prospective survey	83
		Retrospective survey	1617
	2.2 Adapted resources for participant recruitment	Participant Information Sheets	25
	2.3 Survey of researcher reasoning	Questionnaires	127
	2.4 Values and opinions of stakeholder groups	Interviews	60

3. Developing guidance to help researchers to include adults with capacity and communication difficulties in research	3.1 Data synthesis	N/A	
	3.2 Development of guidance	N/A	
	3.3 Pilot of digital learning object	Questionnaires	31

Findings



Stage 1. The law and ethics in research

1.1 The Law

We found that the **Mental Capacity Act** focused on **treatment, welfare** and **decisions about finance**.

The **Mental Capacity Act** was **not focused on research**.

Not a lot was said about **research in the Mental Capacity Act**.

It is **not helpful** to make **researchers** undergo **series of test** in order to **get approval for research** involving **people with capacity and communication difficulties**.

More **focus** is on **protecting people** with **capacity and communication difficulties** than **empowering** them in **research**.

Those who **lack capacity** require a **consultee**. A **consultee** to say their **likely wishes about research**.

There is **doubt about** how **effective** it is to ask a **consultee** about the **likely wishes** of those who **lack capacity**.

There is also **doubt** about **obtaining the final approval** from the **Research Ethics Committee**.

One of the **reasons** is that it is **not always practical** to ask a **consultee** to **speak on behalf** of **participants who lack capacity**.

Instead, **researchers** should **be encouraged** to **work directly** with the **person who lacks capacity**.

Researchers should **focus** on the **wishes** and **feelings** of those with **capacity and communication difficulties**.

It is **better** that those with **capacity and communication difficulties** can **express** their **agreement or disagreement**.

In **this way**, those with **capacity and communication difficulties** are **supported** to make their **own decisions**.

Also, very **little is known** about how **Research Ethics Committee** forms its **opinion** and what is in the **minds of its members** when **decisions are made** about a **project**.

Differences in the way **decisions are made** by the various **Research Ethics Committees** could lead to **inconsistency** in their **decisions**.

The **differences in** the way **decisions** are made by the various **Research Ethics Committees** could **reduce** the **trust placed** in the **committees**.

The way **research requirements** have been written **creates the impression** that there are different duties for the **researcher**, the **consultee** and the **Research Ethics Committee**.

The **duties** of the **researcher**, the **consultee** and the **research ethics committee** are **similar**.

The **confusion** around the **duties of** the **researcher**, the **consultee** and the **research ethics committee** are **disappointing** for the **researcher** when it comes to the approval **process**.

Researchers may be **unwilling** to **consider** those who **have capacity and communication difficulties** in **research**.

1.2 Policy Guidance

The **Health Research Authority document** and the **Code of Practice (CoP)** both mentioned **conditions** where people may have **capacity and communication difficulties**. The documents mentioned:

- **aphasia**

- intellectual disability
- autism
- dementia.

In the **category inclusion in research**, words mentioned a lot were **to do with**:

- risk
- benefit
- protection

Words that was **not mentioned** a lot were **to do with**:

- empowerment
- autonomy

Only the **Health Research Authority** documents **had words** to do with the **use of media**.

Words with **media** was **used to improve** the **understanding** of **those** with **capacity and communication difficulties**.

We examined **14 documents** written by **different authors**. We also looked at the **Code of Practice**.

What was in the documents could be put into three groups:

- **Ethics**
- **Capacity & Decision-making**
- **Accommodations.**

Please see the **figure 1** on **page 23**. **Figure 1** shows the **number of times** the **group of words** were mentioned.

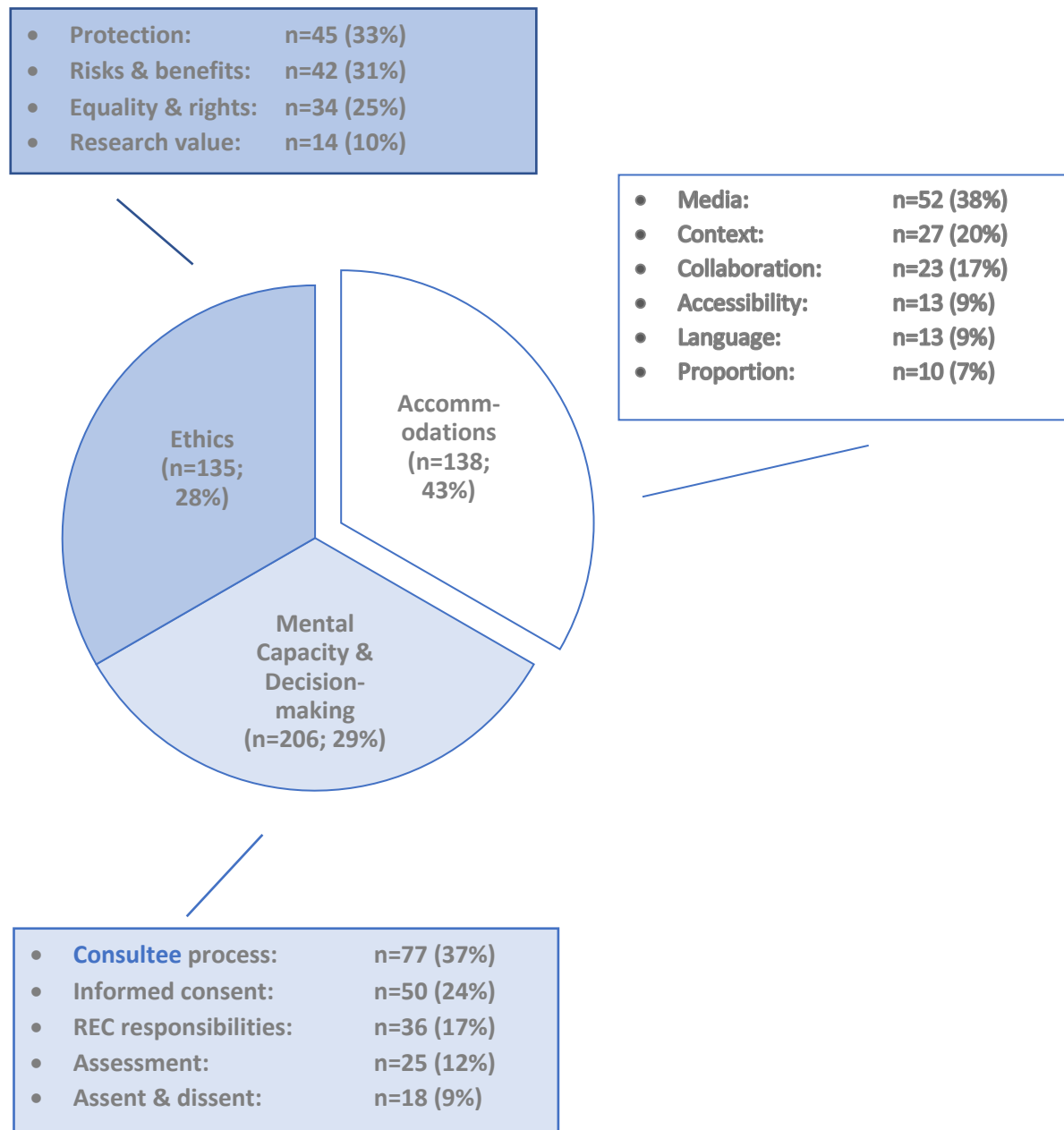
There was **connection** between **Ethics** and **Capacity & Decision-making**.

Ethics focused on the **moral principles** responsible for **actions** and **decisions** in relation to **research**.

Capacity & Decision-making describes the **process** used to **include** people in research.

Accommodations focused on things that could be done to **support** the **participation in research** of people **with capacity and communication difficulties**.

Figure 1. Number of times items were mentioned



Capacity & Decision-making was mentioned a lot in the **research guidance**.

Ethics was **mentioned most** in the **Code of Practice** (2007).

When **ethics** was **mentioned** in the **Code of Practice**, it was about how the **Mental Capacity Act** should be **used for 'protection' and 'risks & benefits'**.

The **Code of Practice** explains the importance of research.

In the **Code of Practice (CoP)**:

Accommodations were **described** in terms of:

- the **context** (such as the environment or situation)
- **language** (choice of words)
- **media** (how information is given).

Accommodations were **presented** as **separate from Ethics** and **Capacity & Decision-making**.

The **Code of Practice** **contained** just **one** general **statement** on the **need for support**.

1.3 How these laws and guidelines have been used by researchers

We reviewed **research studies** carried out in **England** and **Wales** from **2007**.

We **included participants** aged **16 years and above** living with **capacity and communication difficulties**:

- **Autism**
- **Stroke**
- **mental health**
- **dementia**

- acquired brain injury
- intellectual disabilities

Reports of **clinical trials** were **not included**.

Twenty-eight studies (28) were **included** as they **met** the **criteria** set for **studies to include**. The **table** on below **show** the **findings**:

<i>Adults with:</i>	Number of studies	Percentage (%)
<i>Intellectual disability</i>	12	42.9
<i>Dementia</i>	9	32.1
<i>Autism</i>	3	10.7
<i>Mental health disorder</i>	2	7.1
<i>Aphasia after stroke</i>	2	7.1
<i>Acquired brain injury</i>	0	0

Findings:

Participants who were **unable to make all or some decisions for themselves** were **included** in fifteen **(15) studies** based on the advice of a **consultee**. They were **excluded** from **7 studies**.

In the other six **(6) studies**:

1 study put in place a system where consultee could give **advice** but in fact **all the participants** were **able to give informed consent**.

The **participants** in the remaining **5 studies** were **able to give informed consent**.

We found that **few studies included adults with capacity and communication difficulties** in **research**. This is despite a **range of adapted materials** and **information sharing procedures** that could support **recruitment**.

Current **guidance** is **used** in research in **different ways**.

The **consultee** process is sometimes **used to include** those who have **capacity and understanding difficulties**.

Other times those who have **capacity and understanding difficulties** are **not included**.

Those who have **capacity and understanding difficulties** are still **not well represented** in **research**.



Stage 2. How research is currently being done

2.1 Survey of review processes by RECs

Prospective survey

We looked at **research applications made to Research Ethics Committees** in **England**. These were **applications** made over a **12-month period**, from **September 2018 to August 2019**.

Information from the **applications** was **collected** by the **Health Research Authority**. It **focused on** the following **sections** of the **application**:

- **Type of people recruited**
- **Criteria for excluding people** that relates to **capacity and communication difficulties**.
- **Information sheets**. This section was used to **identify accommodations and adaptations** made to communicate research information with potential participants.

Findings:

Participants.

Just **over half** the **applications** focused on **adults with dementia**.

In the table below we show the **groups of adults with capacity and communication difficulties** included in research applications.

<i>Adults with:</i>	<i>Number of studies</i>	<i>Percentage (%)</i>
Dementia	42	50.6
Acquired brain injury	21	25.3
Intellectual disabilities	6	7.2
Aphasia after stroke	5	6
Mental health disorders	5	6
Autism	4	4.8

Exclusion criteria.

Around **half** did **not identify** any **exclusion criteria** relating to people with **capacity and communication difficulties**.

Of the **exclusion criteria** in the applications:

- **18** related to a **lack of capacity**
- **5** related to **communication difficulties**
- **11** related to **lack of a consultee**
- **17** related to **limited English language skills**.

Accommodations:

There were **various accommodations** used when **people with capacity and communication difficulties** were **asked to take part in research**.

The **Participant Information Sheets** was **adapted** in **46 different ways**. It was the **design** and **what was included** that was **adapted**. For example:

- the use of **pictures or images**
- the use of **large print**.

In **21 applications**, the **researchers** had **written** how they were going to give **information to participants**. For example:

- i) **giving verbal explanations** when interacting with **potential participants**.
 - ii) **talking slowly**
 - iii) **using simple words**
 - iv) **repeating what was said**.
-
- In **25 applications**, **extra support** from the **family, carers** and **others** was thought about.
 - in **5 applications**, the use of a **consultee** was **reported**.
 - in **15 applications**, researchers put in place a system to check **assent** or **dissent** of **participants lacking capacity**.

Retrospective survey

We looked at research **applications from the past** that was **recorded on** the **website** of the **Health Research Authority (HRA)** between **2012-2017**. The research applications on the **Health Research Authority (HRA)** website is **available** to **everyone**.

Findings:

1617 research **applications** included **people with capacity and communication difficulties**.

Participants:

The **research applications** were about:

- **mental health conditions** in **521 applications**.
- **dementia** in **514 applications**.
- **traumatic brain injury** in **248 applications**.
- **aphasia after stroke** in **229 applications**.
- **intellectual disabilities** in **136 applications**.
- **autism** in **107 applications**.

Grouping of research applications

We used the **World Health Organisation system** to put the **studies** we found into **groups**. There were three groups of studies:

- **activities & participation**
 - **body function & structure**
 - **environment**
-
- **Most studies** were about '**activities & participation**'.
 - **389 studies** were about **activities & participation** only.
 - **622 studies** were about **activities & participation** but also **connected to** some form of **intervention**.

Studies about **activities & participation** that was **connected to** some form of **intervention** was **placed in** the **group** called '**environment**'.

152 studies were about '**body function & structure**' only.

177 studies were about '**body function & structure**' as well as **intervention**.

120 studies were about '**body function & structure**' as well as '**activities & participation**'.

We looked at the decisions made by **Research Ethics Committees**. The decisions were **similar** across **all groups** with **capacity and communication difficulties**.

- 7% received **unfavourable opinion**
- Less than 1% received **unfavourable decision even after further information was given by the research team**
- 30% received **favourable opinion** at their first application
- 63% received **favourable opinion after the research team has given further information**.

2.2 Adapted resources for recruiting participants

We asked research teams who had **included people with capacity and communication difficulties** in their research for their **participant information sheet**.

We received **30 Participant Information Sheets** from **researchers** who had included **people with capacity and communication difficulties** in their **research**.

5 Participant Information Sheets were not included. This is **because what was in the Participant Information Sheets had nothing to do with adults with capacity and communication difficulties**.

We **included 25 Participant Information Sheets.**

Findings:

The 25 Patient Information Sheets include:

- **12** for people with **dementia**
- **8** for people with **aphasia after stroke**
- **2** for **adults with intellectual disabilities**
- **2** for **adults with mental health disorders**
- **None** for **adults with autism**
- **None** for **adults with acquired brain injury.**

Presentation of **Participant Information Sheets:**

The **majority** were prepared as **Microsoft word documents.**

Two (**2**) used a **PowerPoint format.**

The **number of pages** of the **Participant Information Sheets** ranged from **1 page to 24 pages** with an **average of 5 pages.**

Pictures:

56% used pictures in the **participant information sheet.**

The **pictures** were different in **different positions** in the participant information sheets.

Half of the **pictures** were **placed** either on the **right of words**, on the **left of words** or **immediately below the words.**

Text font:

60% used a **font point size greater than 12.**

Format:

- **All except 1 Participant Information Sheet used Sub-headings.**
- **28% of the Participant Information Sheet used bullet points**
- **20% of the Participant Information Sheet used numbered lists**

The **number of words** and **sentences** in the **Participant Information Sheet** were very different. We looked at these features in **the Participant Information Sheet**:

- **familiarity** - *how familiar a word seems to an adult.*
- its **concreteness** - *how concrete or non-abstract a word is.*
- **imageability** - *how easy it is to make up a picture in the about of the word.*

The **words used** were **generally familiar**. Although the **concreteness** and **clarity** of the **images** were **lower**.

The **reading ease score** for **information sheets** was around **67.7** on a **0 to 100 scale**. **0 on the scale means very difficult while 100 on the scale means very easy**. This was very **different across** the **information sheets**.

2.3 How do researchers make decisions

127 researchers responded to our **online survey** about their **use of the Mental Capacity Act** within their research studies:

- **Just over 50% of researchers** reported having **worked with people** who have **capacity and communication difficulties** for **more than ten years**.

- **Just over 50%** of **researchers** also reported having **more than ten years of experience** working in research.
- **Just over 80%** reported that they thought their **knowledge of the Mental Capacity Act** was **good to excellent**.
- **78%** of **researchers agreed** that they **felt confident** when working with a **consultee**.

Most researchers said they included **people who have difficulties with capacity and communication** within their **research**.

Researchers included **people who have difficulties with capacity and communication** because their **project** was **specifically** about.

Researchers also said that including **people who have difficulties with capacity and communication** was to **improve** the **quality of research**.

Researchers said that **Including people who have difficulties with capacity and communication** in research was also to **give people who have difficulties with capacity and communication a voice**.

Researchers used a **variety of communication aids** and **accommodations** to **support people who have difficulties with capacity and communication** to take part in research. These include:

- **Increasing their use of hand and body gestures** when **communicating** with **people who have difficulties with capacity and communication**.
- Using **easier to read text**

- being **flexible** about the way research was conducted and **offering breaks**
- making sure to **ask participants about their needs**.

About **35%** of researchers reported that they **did not make use of any communication aids** within their research projects.

Some researchers had **knowledge** about the **Mental Capacity Act** as it is used in **clinical settings**.

Researchers had **some confidence** in **assessing capacity** in **clinical settings**.

The findings show that researchers were **not sure** about some aspects of the **application of the Mental Capacity Act** within **research settings**. For example:

- **Some researchers are confused** about the **role** of a **consultee**
 - some researchers **confused** the **role** of a **consultee** with that of **an advocate**,
 - some researchers **confused** the **role** of a **consultee** with a **best interest assessment** within a **clinical setting**.
- **Some researchers** were **not sure** if the **assessment of capacity** was **their responsibility** or the **responsibility** of **those involved in the provision of care**.

2.4 Views and opinions of groups interested in inclusion

Group 1: Adults with capacity and communication difficulties:

The **inclusion** of **adults with capacity and communication difficulties**:

- **Adults with capacity and communication difficulties** thought they should be **included in research**.

Adults with capacity and communication difficulties thought that **including them in research**:

- **will improve understanding** of how the conditions affect them.
- will **make research** more **comprehensive**.
- will also **give them a voice**.

Adults with capacity and communication difficulties identified **benefits** to them if they take part in **research**. These include:

- feelings of **altruism**
- a **sense of achievement**
- and **feeling useful**.

Adults with **capacity and communication difficulties** expressed anger about **excluding** them in research.

Excluding people with **capacity and communication difficulties** gave them **a sense**:

- of being '**disregarded**' or '**locked out**',
- of **discrimination**
- that **their issues would not be recognised**.

Excluding people with capacity and communication difficulties is partly **responsible** for **making them feel invisible**.

Some **disabilities** are **associated with feeling invisible**.

The Mental Capacity Act

Some **adults with capacity and communication difficulties** were **concerned about** the **Mental Capacity Act** (2005). The **concern** is to do with the **process of selecting a consultee**.

Other **adults with capacity and communication difficulties** thought the **consultee** process was **beneficial**.

It is beneficial if it meant **more people could be included** in research.

Adults with capacity and communication difficulties said:

- they would want to **be involved** in the **consultee** process as much as possible.
- that the **consultee** should be **someone who knew them well**.
- that people who **can't communicate** are **thought not to understand** and **are not noticed**.

Group 2: Supporters and practitioners:

Exclusion

Most **healthcare professionals and those who support or care for adults with capacity and communication difficulties:**

- thought it was **wrong to leave adults with capacity and communication difficulties out of research**.
- felt that leaving **adults with capacity and communication difficulties out of research** meant that **assumptions are made about their experiences** which may **not be right**.
- thought **researchers** should **make more effort** to make **research participation accessible**. For example, **engaging more with people** who take part **in research** and use **observations** from their **everyday lives**.
- felt **that providing one to one support helps people with capacity and communication difficulties to take part**.

Mental Capacity Act

- Some **healthcare professionals** and **those who support or care for adults with capacity and communication difficulties** were **not familiar** with the **consultee** process.
- Several of **those who support or care for adults with capacity and communication difficulties** felt they **wouldn't want to speak for someone else**.
- There was a **view** that **researchers** would rather be **careful**.
- **Gatekeepers** did not see themselves as too careful.
- When a **gatekeeper** felt a research is not good for the participants, they will **choose not to pass information** about the research **on**.

- Other **gatekeepers** looked **for research opportunities** for those in the group they supported.
- Researchers assessing **capacity** should have the **communication skills** to be able to **adapt** the research **information** to the **individual**.

Group 3: Researchers and ethics committee members

Researchers and **ethics committee members** thought that it was **morally good** to **involve adults with capacity and communication difficulties** in research.

Ethics committee members thought that **researchers** who apply for **approval** for their research **understood** the **main principles** of the **Mental Capacity Act**.

Ethics committee members themselves struggled with the difference between **personal** and **nominated consultees**.

Ethics committee members felt the **Health Research Authority** was too **focused on writings** and **signatures**.

Researchers and Ethics committee members agreed that **information sheets** should be “easier to read”.

It was **not clear** that **researchers** are **committed to** using all the **different methods** for **supporting people** to make their **own decisions**.

Only a few **researchers and ethics committee members** understood that **under the Mental Capacity Act**, lots of effort should be made to **support people to make their own decisions**.

Few **researchers and ethics committee members** understood in addition to having a consultee, a **person judged to lack capacity** should still **be involved in** the **decision-making process**.



Conclusions from Stages 1 and 2

- The **law and ethics** for **research** in **England and Wales** is informed by the **Mental Capacity Act** (2005) and the **Code of Practice** (2007).
- For those who lack capacity, the **Mental Capacity Act** deals with their **treatment, welfare** and **financial decisions**.
- What is written about research in the **Mental Capacity Act** is **poorly written**.
- **It makes it difficult** for researchers **to balance protection and empowerment**
- The **Code of Practice** (2007) provides some **explanations** of the **practical parts** of the **Mental Capacity Act**.
- The **Code of Practice** (2007) include processes to do with **protection** and **risk management**.
- **MCA REC members, researchers and consultees** all have **parts to play** in the **ethical approval process**.
- The **duties** of the **MCA REC members, researchers and consultees** go against each other.
- There **are insufficient plans** and **practical** guidance to support how **duties** should be carried out by **MCA REC members, researchers and consultees**.
- **Few studies** were **linked** to the **Mental Capacity Act**.

- Few studies had adults with capacity and communication difficulties as participants.
- People with capacity and communication difficulties are not well represented in research because:
 - there is occasional use of consultees
 - they are often excluded in research

Our review of **current Practice** showed that:

- **intrusive research** under the **Mental Capacity Act** is mostly focused on participant '**activities and participation**' and **interventions**.
- **Intrusive research** had a lesser focus on '**body functions and structure**'.
- Individuals that **lack capacity** were **included** in research because of their **presence in the target population**.
- They **continue** to be **excluded** based on a **lack of capacity**.

To include **people with capacity and communication difficulties** in research:

- researchers use **different types of materials and resources**.
- researchers also use **different types of processes** support their **understanding** of the planned **research**.

Most **recruitment procedures** still involve the use of **written information** to pass on project **information**.

It is not clear that **researchers' access to resources makes a difference** in the way words are used **in participant information sheets**.

Information presentation in participant information sheet by researchers is **not consistent**.

Consultees:

For **those who lack capacity**, **consultees** give advice on the likely **wishes** and **feelings** about participation.

Consultees are **used in different ways** when it comes to **adults with**:

- **intellectual disabilities**
- **autism**
- **dementia**
- **acquire brain injury**
- **aphasia after stroke**
- **mental health disorders**.

Researchers are **confused** about the **responsibilities** and the duties of **consultees**.

When a **consultee** is involved, those who **lack capacity** are **hardly involved in the decision-making process**.

Recommendations from Stages 1 and 2

1. Promotion of cooperation between the researcher and the participant

The **system for including adults with capacity and communication difficulties** in research **needs to be reconsidered**. This means that:

- **cooperation between the researcher and the participant should be promoted.**
- **cooperation between the researcher and the participant** should be done **in a way that the participant feels empowered and protected.**
- **importance** should be **placed on researchers** to get **expressions of agreement** from the **participant**.
- **expressions of agreement** from the **participant** may be a **better way of supporting decision-making** for the participant.

2. Support for participant to make their own decision

There is a **strong** and **ongoing need for guidance** that focuses on the **researcher's efforts** on **supporting participants** to **make their own decision**.

- **Participants** should be **supported to make their own decisions** as much as possible **even if they lack capacity**.
- **Participant** should also be **supported** as much as possible *to make their own decision* even **if a consultee is involved**.
- **Adaptations** and **accommodations** should be **used as much as possible** to **support decision making** for **people with capacity and communication difficulties**.
- **Supporting** them to make their **own decisions** will **ensure** that they are **included in research** and that their **voice is heard**.

3. Use of a full range of adaptations & accommodations

Researchers should **use adaptations** and **accommodations** when working with **adults who have capacity and communication difficulties**.

Adaptations and **accommodation** support people to use their available skills as far as possible.

In research, **adults with capacity and communication difficulties** need to be **supported to use** their **skills** to:

- **understand information,**
- **retain information**
- **weigh information up**
- **and communicate their decision.**
- **Researchers** and **ethics committee members** need to know about the different **ways to support those with capacity and communication difficulties** to **make their own decisions**.
- **Knowing** the **different ways to support autonomous decisions** will enable ethics committee members to advise those applying to seek ethical approval for their research.
- **Traditional ways** of obtaining informed *consent* are **not appropriate for all**.
- There is a need to **think of other ways to obtain informed consent**.



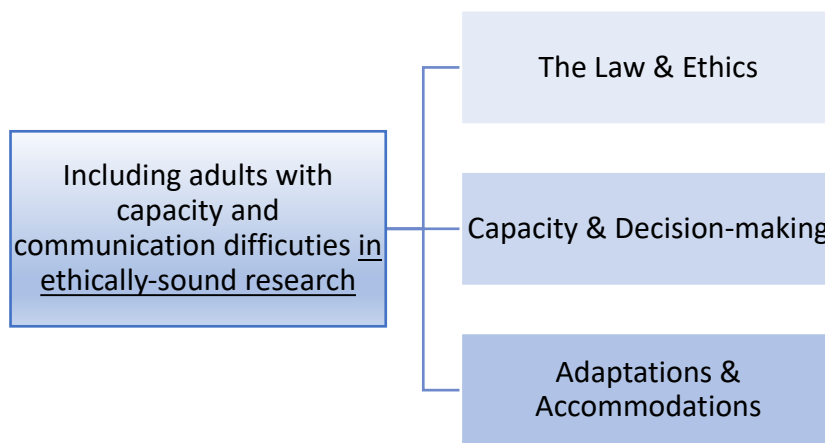
Stage 3. Developing guidance to help researchers to include adults with capacity and communication difficulties in research

The **final stage** of the project **focused** on **developing guidance** to help **researchers** to **include adults with capacity and communication difficulties** in **research**.

This **guidance** was based on the **recommendations** from **stages 1** and **2** of the project. These were:

- **promotion** of cooperation between the **researcher** and the **participant**.
- **cooperation** between the researcher and the participant.
- support for **participant** to make their own decision
- **use** of all the **different types of adaptations** and **accommodations** that can **support adults with capacity and communication difficulties** to be involved in research.

The **content** of the **guidance** was **based on** the **findings** of the project and **organised in three key groups** shown in the diagram on the next page.



This guidance was put in a **Reusable Learning Object (RLO)**. The **aim** was to support the **interest** of a **wide range of people to use** including:

- **researchers**
- **research ethics committee members**
- **user-focused organisations** as potential **consumers of research**.

Guidance development:

A **first draft** of the **content** of the Reusable Learning Object was completed in **PowerPoint format**.

An **explanation** was then **written** to go with it.

The **explanation** described how those who would use it would move through the Reusable Learning Object.

The **PowerPoint format** also included **pictures** and **animations**.

At this stage, the proposed **content** of the Reusable Learning Object was **shared** with **representatives** of the **Working Group**.

The **Working Group** had the **opportunity** to **make comments** and **suggestions on the Reusable Learning Object**.

The **comments** and **suggestions** were then **used** to **further develop** the **Reusable Learning Object**.

This **Reusable Learning Object** was then **made into** an **online version**.

The **work** was **carried out** by an **independent digital learning company**.

Examples from the **Reusable Learning Object** were regularly sent **out** to the project **team** to look at and made their thoughts known.

An **online questionnaire** was developed to **ask for the thoughts** of those interested in **testing** the **Reusable Learning Object**.

This is known as the **evaluation** part of the project.

The following people helped us to evaluate the Reusable Learning Object:

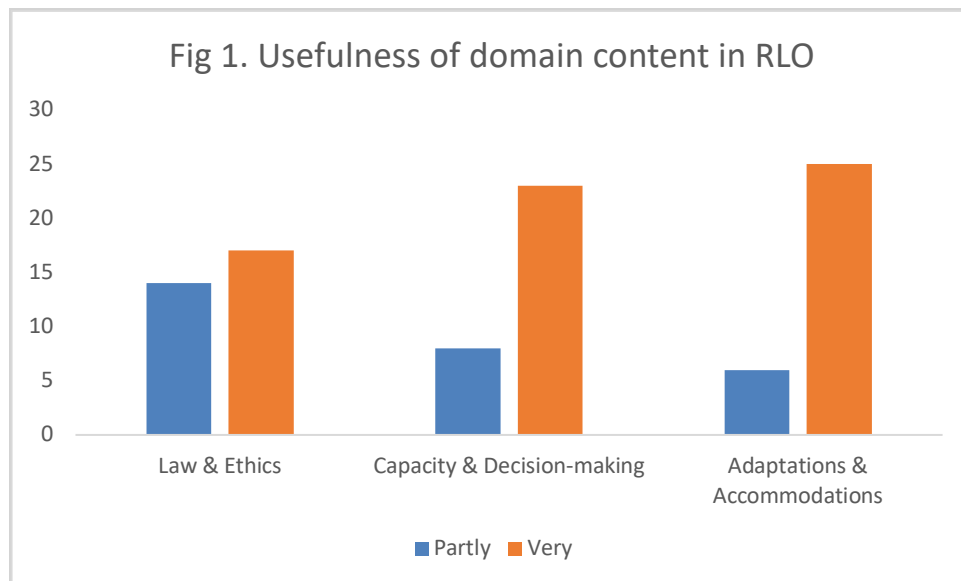
- **Researchers**
- **Research Ethics Committee members**
- **Adults with capacity and communication difficulties**
- **Member of user-focused organisations**

We received **31** completed **questionnaire** on the **Reusable Learning Object**. People who took part were mostly:

- **women**
- **people over the age of 54 years**
- **white**
- **researchers**

Those who took part were asked to rate **how useful each part** of the **Reusable Learning Object** is.

‘Adaptations and Accommodations’ was rated as **the best**. This was **followed by ‘Capacity and Decision making’**. **‘Law and Ethics’** was rated the **least useful**.



Those who completed the questionnaire **suggested** that:

- **more** examples of different **cases** should be **added to the Reusable Learning Object**. **Examples** of how to **involve participants** in **research**. **Examples** of how to **make language easy to understand**. **Examples** of how to **work with consultees**. **Examples** of how to make note of **participants agreement** and **participants disagreement**.

- The **Reusable Learning Object** should be **easy to go through**. Those who use the **Reusable Learning Object** should be able to **track their journey through the guidance**.
- **Words** used in the **Reusable Learning Object** should be **easy to understand** for everyone.

Recommendations from Stage 3

To make the **Reusable Learning Object** even better, we need to **ask many more people what they think** of it.

There is need to add **more examples of cases**:

- that show how to involve **people with capacity and communication difficulties** in **research**;
- how to document **participant's agreement** or **assent**;
- how to document **participant's disagreement** or **dissent**.

The **full report** can be downloaded from the project website:

<https://www.uea.ac.uk/groups-and-centres/assent>