

# Decision-making competence in people with learning disabilities: can accessible information make the difference between consent and informed consent?

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/11/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Annetta Bouius

### Contact details

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London  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Study objectives

What are the factors that influence the decision-making abilities of people with learning disabilities? How can decision-making skills and abilities of people with learning disabilities be enhanced through the way in which we explain information?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

### Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Learning difficulties

### Interventions

1. Hypothetical dental procedure explained to participants using verbal method of explanation
2. Same dental procedure explained using equivalent accessible information form of explanation, interviews

### Intervention Type

Other

### Phase

Not Applicable

## Primary outcome measure

Informing an individual in a way that works with their skills and abilities would ensure that individual is given every opportunity to participate in the decisions being made in their lives.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2003

**Completion date**

31/12/2003

## Eligibility

**Key inclusion criteria**

15-20 healthy volunteers who are service users of a range of services which provide services for people with learning disabilities, including Centre 404, Elfrida Society, Islington Learning Disabilities Partnership, etc.

**Participant type(s)**

Healthy volunteer

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

20

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

31/12/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Islington Learning Disabilities Partnership**  
London  
United Kingdom  
N7 8SU

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

North Central London Community Research Consortium (UK)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration