

# A randomised controlled feasibility trial of the Books Beyond Words intervention to improve the management of epilepsy in people with learning disabilities

<b>Submission date</b> 23/04/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/04/2014	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 16/03/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

A randomised controlled feasibility trial of the Books Beyond Words intervention to improve the management of epilepsy in people with learning disabilities

### Acronym

Wordless Intervention for Epilepsy in Learning Disabilities (WIELD)

### Study objectives

Epilepsy is the most common health problem that affects people with learning disabilities. It is more complex, more severe, and leads to more deaths in people with learning disabilities than in the general population who live with epilepsy. People with epilepsy and learning disabilities find it difficult to manage their illness. They do not have easy access to services and struggle to manage repeated seizures. They are often resistant to treatment, which can lead to premature deaths and increased costs. The guidelines of the National Institute for Health and Care Excellence recommend that patients with learning disabilities and epilepsy are offered the same standard of care, services and investigations as the general population.

The Books Beyond Words booklet for epilepsy uses images to help people with learning disabilities better understand and manage their condition and improve their quality of life. This intervention has never been formally evaluated and its effectiveness remains unknown. Given the lack of research in this area, it is recommended that this intervention is evaluated in a feasibility trial. This will determine whether a larger trial can be undertaken and what sample size, design and methods are most appropriate. The acceptability, potential effectiveness and cost effectiveness of using the booklet for epilepsy will also be explored. Eligible patients with epilepsy and learning disabilities will be randomised to receive either the Books Beyond Words booklet for epilepsy or routine information and care. In the intervention group, the booklet will be used at the Epilepsy Clinic with a Research Nurse and Carer, and later at home with the carer or family. Outcomes will be measured at 1, 3 and 5 months. Semi-structured interviews will also be used to assess the feasibility and acceptability.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

MREC;17/04/2014; ref. 14/WA/0135

### Study design

Randomised; Interventional; Design type: Treatment

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Managing epilepsy in people with learning disabilities

## **Interventions**

The Books Beyond Words booklet: Getting on with Epilepsy, uses pictures to tell a story about a young man with learning disabilities and epilepsy who progressively learns how to better manage epilepsy and recurrent seizures. All images have been tested with people with mild and severe learning disabilities to ensure understanding. The intervention aims to improve seizure control, reduce the risk of falls and seizure-related injuries, and improve quality of life. It also aims to illustrate best

Follow Up Length: 5 month(s); Study Entry : Single Randomisation only

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Quality of life [Epilepsy and Learning Disabilities Quality of Life (ELDQOL) scale]; Timepoint(s): baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)

## **Secondary outcome measures**

1. Demographic data; Timepoint(s): Baseline (T0)
2. Discontinuation rates; Timepoint(s): baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)
3. EQ-5D; Timepoint(s): Baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)
4. Feasibility and acceptability of study procedures and intervention; Timepoint(s): week 20 (T3)
5. Intervention's patterns of use; Timepoint(s): baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)
6. Rates of recruitment; Timepoint(s): Baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)
7. Resource use; Timepoint(s): Baseline (T0), week 20 (T3)
8. Seizure control; Timepoint(s): Baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)
9. Seizure severity; Timepoint(s): Baseline (T0), week 4 (T1), week 12 (T2), week 20 (T3)

## **Overall study start date**

01/07/2014

## **Completion date**

29/02/2016

# Eligibility

## Key inclusion criteria

1. Male and female patients, over 18 years of age
2. A confirmed clinical diagnosis of epilepsy (according to medical notes) and at least one seizure over the past 12 months
3. A confirmed clinical diagnosis of a learning disability (significantly below-average general intellectual functioning and an IQ below or equal to 70)
4. Ability to communicate verbally. The patient has a vocabulary of more than 10 words and can use 1 to 2 words, or more, to communicate
5. The carer is sufficiently proficient in English to read and complete the questionnaires with the patient

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

## Key exclusion criteria

1. Vision impairment
2. Confirmed diagnosis of dementia
3. Has used the Books Beyond Words booklet for epilepsy in the past 12 months

## Date of first enrolment

01/07/2014

## Date of final enrolment

29/02/2016

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**College Lane**  
Hatfield  
United Kingdom  
AL10 9AB

## **Sponsor information**

### **Organisation**

Hertfordshire Partnership Foundation NHS Trust (UK)

### **Sponsor details**

99 Waverley Road  
St. Albans  
England  
United Kingdom  
AL3 5TL

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/0128dmh12>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB); Ref.: PB-PG-0213-30042

## **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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	20/11/2014		Yes	No
<a href="#">Results article</a>	results	10/11/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No