

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

Submission date 23/04/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/04/2014	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 16/03/2020	Condition category 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

Protocol serial number

16588

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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

College Lane

Hatfield

United Kingdom

AL10 9AB

Sponsor information**Organisation**

Hertfordshire Partnership Foundation NHS Trust (UK)

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

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?
Results article	results	10/11/2016		Yes	No
Protocol article	protocol	20/11/2014		Yes	No
HRA research summary			28/06/2023	No	No