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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

Registration date
23/04/2014

Overall study status
Completed

Last Edited
16/03/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes