ISRCTN11409097 https://doi.org/10.1186/ISRCTN11409097

READ-IT feasibility study: Teaching early reading skills to adults with intellectual disabilities using a support worker/family carer mediated on-line reading programme

Submission date
04/12/2019

Recruitment status
No longer recruiting

Registration date
07/01/2020

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Many people with intellectual disabilities (ID) (also called learning disabilities (LD)) find it difficult to learn to read. This limits their ability to do things independently. Instead, they often need other people to help them complete everyday activities. “Easy Read” is sometimes used to help make information easier to understand. But this “one-size-fits-all” does not work for everyone. Another way of helping may be to teach people with LD to read. If we can teach adults with LD to read, it is possible that they will be able to do more things by themselves and will have a better quality of life.

The researchers have developed a reading programme called 'Teaching early reading skills to adults with LD' (READ-IT) based on work that they have done teaching children with LD to read as well as a small project with adults with LD. With READ-IT, adults with LD will take part in an on-line reading programme with additional support from their support workers or family carers using a guide that they will help to produce.

Who can participate?
Any adult with a LD can take part if they can make the decision to take part and have some basic computer skills. They also need to have a support worker or family carer who is happy to support them. Everyone who takes part will be asked to complete some measures of things that may change during READ-IT.

What does the study involve?
Adults with LD will be put into one of two groups by chance. One group will be taught to read using READ-IT, the other will have no change to their day-to-day activities. The intervention consists of 80 online episodes delivered in sessions of approximately 20 – 25 minutes, and it's recommended that between 3 and 6 sessions taking 20 to 25 minutes are completed per week. READ-It will therefore be delivered on average over 16-20 weeks. Participants will complete questionnaires at the start and at a six month follow up.

After READ-IT has been completed, the researchers will also interview some of the adults with LD, their support workers and family carers, to find out why they decided to take part and about their experiences having taken part in the study.

What are the possible benefits and risks of participating?
The people with LD that take part in this research study who are put into the READ-It group will have an opportunity to learn to read and anyone supporting them will receive training in supporting others to learn to read. Those participants who are in the activity as usual group will be given an opportunity to learn to read once the study has been completed.
The risks to taking part in the study are minimal, participants will be asked to use some of their spare some time to fill out questionnaires, possibly take part in interviews, and to complete the intervention (if in the intervention arm). Should trial staff become concerned at any point about the well-being or safety of a participant or their support worker/family carer, they will be offered the opportunity to withdraw from the trial without any repercussions.

Where is the study run from?
University of Warwick, UK

When is the study starting and how long is it expected to run for?
December 2019 to January 2022 (updated 31/03/2021, previously: March 2021)

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
Dr Elinor Coulman, Johne1@cardiff.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Elinor Coulman

Contact details
Research Fellow / Senior Trial Manager
7th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)29 20687624
johne1@cardiff.ac.uk

Type(s)
Scientific

Contact name
Dr Elinor Coulman

Contact details
Research Fellow / Senior Trial Manager
7th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF144YS
+44 (0)2920687624
johne1@cardiff.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
271739

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
v1.0, IRAS 271739, CPMS 44540

Study information

Scientific Title
Teaching early reading skills to adults with intellectual disabilities (READ-IT) using a support worker/family carer mediated on-line reading programme – a feasibility study

Acronym
READ-IT

Study objectives
Primary objective: To examine whether READ-IT can be delivered successfully by community support workers/family carers.
Secondary objective: Whether it would be feasible to conduct a later definitive RCT of the effectiveness and cost effectiveness of READ-IT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2019, NHS Health Research Authority, London - Camberwell St Giles Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8124; NRESCommittee.London-CamberwellStGiles@nhs.net), ref: 19/LO /1784

Study design
Individually randomized feasibility study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Adults with intellectual disabilities (ID) with poor reading abilities

Interventions
This will be an individually-randomised feasibility study of adults with ID. We will recruit individuals from family homes, independent living, and small group settings (e.g. supported living and residential homes) and randomise them 1:1 to receive the READ-IT intervention or usual practice. Individuals will be randomised in a 1:1 ratio using a randomisation programme developed by the Centre for Trials Research. The randomisation list will be prepared using the Stata command 'ralloc'. Allocations will be balanced by setting type (family home vs. other social care setting). The Study Manager/Research Assistant will inform participants of their allocation by telephone and will provide all details of starting the READ-IT course to those allocated to the intervention arm.

The study will be composed of three stages:

STAGE 1: Intervention Refinement and Development:
A new intervention (READ-IT) will be developed by further adapting the Headsprout® Early Reading program (HER®) support manual specifically for use with support workers and family carers.

STAGE 2: Feasibility study:
The intervention arm participants will participate in an online reading programme (READ-IT) supplemented by additional support strategies tailored for adults with ID. The control arm participants will experience usual practice in relation to the support of their reading.

Baseline measures for all participants will be conducted prior to randomisation and repeated 6 months post-randomisation. Selected participants will be approached 6 months post-randomisation to take part in a qualitative study designed to address the progression criteria that will not otherwise be clear from other data collected.

A placement assessment to assess where within the intervention the individual is best advised to start will be used for eligibility screening across all participants prior to baseline data collection (but during the same visit). If eligible and willing to take part, a baseline interview will be undertaken and informed consent and baseline measures are taken.

STAGE 3: Logic model/full trial protocol:
The findings from the feasibility study will be used to review and refine the logic model and, subject to the progression criteria being met will lead to the development of a protocol for a full trial. This will be achieved through additional Public and Patient Involvement (PPI) input and with the advisory group.

Intervention Type
Other

Primary outcome(s)
The feasibility of using a range of established outcome measures, proposed to test the intervention in a main trial, will be assessed:
1. Literacy measured using dynamic Indicators of Basic Early Literacy Skills (DIBELS) questionnaire at baseline and six-month follow-up
2. Reading self-efficacy using a novel questionnaire designed as part of the Patient and Public Involvement (PPI) workshops at baseline and six-month follow-up
3. Carer efficacy in supporting the person to read using a novel questionnaire designed as part of the Patient and Public Involvement (PPI) workshops at baseline and six-month follow-up
4. Quality of Life measured using the EQ5D-5L at baseline and six-month follow-up
5. Wellbeing measured using the Personal Well-Being Index Intellectual Disability version, completed by the person with ID and the family member/support staff member at baseline and six-month follow-up
6. Costs measured using the Client Service Receipt Inventory (CSRI) at baseline and six-month follow-up
7. Adherence to the READ-IT intervention measured using software that tracks progress through the intervention through the study and at six-month follow-up
8. Fidelity of READ-IT intervention delivery measured using a READ-IT self-rating of adherence tool during follow-up

Key secondary outcome(s))
1. Recruitment rates measured via management data during recruitment
2. Feasibility of randomisation measured using qualitative interview post six-month follow-up
3. Retention rates measured via management data during follow-up to six months
4. Assessment of the barriers and facilitating factors for recruitment and engagement from the perspective of all stakeholders measured using qualitative interview post six-month follow-up
5. The acceptability of the established primary outcome measures measured using qualitative interview post six-month follow-up)
6. The views/experiences of adults with ID: regarding the READ-IT intervention and study processes measured using qualitative interview post six-month follow-up
7. The views/experiences of support workers and family carers delivering the READ-IT intervention and study processes measured using qualitative interview post six-month follow-up

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Adults administratively defined as having an ID (i.e., through receipt of/being known to services)
2. Have the capacity to give informed consent
3. Have a level of competence in understanding English suitable to access Headsprout® Early Reading program (HER® [assessed using the HER® placement test])
4. Can sound out words (although degree of articulation will not be a factor). (This is a requirement of the HER® component of the intervention)
5. Have access to appropriate internet-enabled technology
6. Either have basic mouse skills, or the capacity to be taught basic mouse skills
7. Are living in a setting in which they are getting daily living skills support supported by a

support worker/family carer
8. Have access to a support worker who are themselves able to read and willing to support the individual for the duration of the study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Visual impairments severe enough to limit their access to computer-based technology even with adaptations

Date of first enrolment
13/01/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Warwick
CEDAR
Westwood Campus
Kirby Corner Rd
University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Elinor Coulman, Johne1@cardiff.ac.uk. Data shared will be anonymised and available from 2023 until 2038 to staff of academic institutions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2025	05/02/2025	Yes	No
Protocol article		22/01/2022	24/01/2022	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes