ISRCTN13633886 https://doi.org/10.1186/ISRCTN13633886

Investigating the acceptability of a school-based programme targeting working memory, attention and language skills in 4-5 year olds

Submission date
05/09/2018

Recruitment status
No longer recruiting

Registration date
07/09/2018

Overall study status
Completed

Last Edited
09/02/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Children from poorer backgrounds often start school with low language ability and attention difficulties, impacting on their school achievement, employment prospects and subsequently on their health. Teams of health professionals (speech and language therapists, occupational therapists, physiotherapists and behaviour specialists) provide school-based programmes to support children with these difficulties, but there is limited evidence of their effectiveness. Recall to Enhance Children's Attention, Language and Learning (RECALL) is an intervention that targets working memory (WM), attention and language skills in 4- 5 year olds. RECALL includes a range of small group and whole-class activities that have been shown to improve WM i.e. sound awareness tasks, complex WM tasks and fantastical play. The programme consists of six, 40-minute sessions that are repeated three times per week for 6 weeks (18 sessions in total). The first session each week will be delivered by the health professionals who will model the activities for the teachers so that they can deliver the two further practice sessions.
The aim of this study is to investigate whether it will be possible to conduct a large-scale research study to investigate the effectiveness of RECALL. In this feasibility study, we aim to investigate:
1. The acceptability of the novel RECALL programme to the health professionals and teachers who deliver it.
2. Whether the programme is delivered as frequently as required and in the way intended
3. Whether we can recruit enough participants to the study
4. Participants' views on the research process
5. Whether comparing RECALL to an existing intervention is appropriate
6. How WM, attention and language skills are typically supported in the classroom (education as usual)
7. Appropriateness and acceptability of the measures used to assess the children's WM, attention and language skills

Who can participate?
1. Health professionals from multi-disciplinary, school-based therapy teams in one region of the UK, Northern Ireland (NI)

2. Six schools in areas of low socio-economic status in NI that have expressed concerns about children's attention and language skills. In each school, one class of year one children (4- 5 year olds) their teachers and classroom assistants will take part.
3. Ten children in each class and their parents/guardians and teachers will be recruited. They will be purposefully selected as follows:
3.1. Five children about whom teachers have concerns around listening and communication skills but do not have a diagnosed developmental or learning difficulty
3.2. Two children with diagnosed developmental or learning difficulties
3.3. Three typically developing children who do not have any identified listening and communication problems

What does the study involve?
RECALL will be compared to an existing programme and to no-intervention (education as usual). The six participating classes will be randomly allocated as follows:
1. Two classes will receive RECALL
2. Two classes will receive a programme currently used by the multidisciplinary school-based teams in NI. This programme has the same number of sessions, duration and format as RECALL and will be delivered in the same way.
3. Two classes will receive their usual education with no additional programme
The teachers in the two intervention groups will not be informed about which programme they will receive. We will measure children's WM, attention and language skills before and after the six-week programme using standardised assessments, a teacher rating of attention skills and a parent rating of communication skills. Direct assessments with the children will be administered by a trained research assistant who will not be told about which intervention they received. At the end of the study, we will explore the health professionals' and teachers' experiences of the programme using short interviews.

What are the possible benefits and risks of participating? (what can participants gain from enrolling, are there any side effects of the treatments and if so, what are the symptoms?)
Participation in this study has potential benefits for the health professionals, education staff and children involved. Prior to delivering the RECALL programme, the health professionals will attend a two-day course that is likely to develop their professional practice. Teachers' knowledge and skills should be enhanced through observing and collaborating with the health professionals. We anticipate that children's skills WM, attention and language skills will be improved by RECALL.
This is a low risk study and no additional potential harm is associated with the research compared to the everyday activity of the participants. Through the whole-class sessions, it is possible that children with neurodevelopmental difficulties may be identified by the health professionals. In this instance the teacher will be advised about an appropriate service to which the child could be referred and asked to seek parental consent prior for referral.

Where is the study run from?
Ulster University (Northern Ireland, UK)

When is the study starting and how long is it expected to run for?
January 2018 to June 2019

Who is funding the study?
Research and Development Division of the Public Health Agency, Northern Ireland (UK)

Who is the main contact?
Anita Rowe
harron-a@ulster.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Anita Rowe

ORCID ID
http://orcid.org/0000-0002-2758-5585

Contact details
Institute of Nursing and Health Research,
Ulster University,
Shore Road,
Newtownabbey,
Co Antrim,
Northern Ireland.
Belfast
United Kingdom
BT37 0QB.

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18/0036

Study information

Scientific Title
A school-based intervention targeting working memory, attention and language skills in 4-5 year olds (RECALL): a cluster randomised feasibility trial

Acronym
RECALL

Study objectives
There has been speculation that working memory (WM) training, embedded within typical educational activities, may improve children’s WM skills and produce transfer effects to real-

world skills such as attention and language. However, little is known about the effectiveness of this approach. 'Recall to Enhance Children's Attention, Language and Learning' (RECALL) is a novel, six-week, whole-class intervention targeting WM, attention and language skills in 4–5 year olds. This feasibility study will explore the acceptability of RECALL to the health professionals and teachers who will deliver it and the feasibility of conducting a large-scale definitive randomised controlled trial of its effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ulster University Research Ethics Committee, 06/06/2018, REC/18/0036

Study design
Interventional multi-centre three-arm cluster randomised feasibility trial

Primary study design
Interventional

Secondary study design
Cluster randomised feasibility trial

Study setting(s)
School

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
Working memory, attention and language difficulties in children

Interventions
Current:
Randomisation is at the school (cluster) level. The six schools will be randomised to each arm of the trial: 2 will receive RECALL, 2 will receive the active control intervention (ALP), and 2 will receive education as usual (control group). This will be conducted by the schools' names being placed in opaque, sealed envelopes, which will be selected by an independent person from within the researchers' institute. Randomisation will occur after baseline data collection with the children.
The school participants (principal, teachers and classroom assistants) and parents/guardians in the two intervention groups will be blinded to their group allocation. Blinding of the health professionals to the schools' allocation will not be possible as the teams will inevitably know which intervention they are delivering. The risk of this influencing the outcomes will be minimised by the blinding of the research assistant (RA) who will be collecting the outcomes data.
The experimental RECALL and active control interventions both incorporate small group and whole-class activities designed to be fun for young children. The programmes are comparable in

their structure, format and dosage (intervention frequency and duration). They consist of six, 40-minute sessions that are repeated three times per week for 6 weeks (18 sessions in total). The first session each week will be delivered by the health professionals who will model the activities for the teachers so that they can deliver the two further practice sessions.
The experimental RECALL programme is a theoretically underpinned, multi-component, manualised intervention that explicitly targets working memory (WM) skills. WM is the ability to hold in mind and mentally manipulate information for short periods of time in the face of distraction. RECALL incorporates evidence-based tasks that are all executive-loaded in nature i. e., the tasks require attentional and processing resources under executive control (not just the simple storage of information). The intervention tasks include: direct, complex WM training; phoneme awareness training; fantastical play; and games targeting inhibitory control.
The active control intervention does not explicitly target WM and is not underpinned by WM theory. It aims to improve children's attention and listening skills through repeated practice at listening tasks. It focuses on teaching children the importance of listening and on the use of visual, verbal and behavioural strategies to support listening e.g., proximal praise. The tasks do not require the children to recall verbal or visuospatial information and they are not all executive-loaded.
To enhance the implementation of RECALL, the health professionals, who will be modelling the programme each week for the teachers, will attend a two-day training course prior to delivering it. To monitor compliance with the programme delivery and dosage, the health professionals and teachers will be asked to keep a simple log of their implementation (e.g., how often they delivered the programme and how long for). To monitor fidelity, three RECALL sessions in each school (one delivered by the health professional team and two by the teacher) will be observed by the research team.

Previous:
Randomisation is at the school (cluster) level. The six schools will be randomised to each arm of the trial: 2 will receive RECALL, 2 will receive the active control intervention (ALP), and 2 will receive education as usual (control group). This will be conducted by the schools' names being placed in opaque, sealed envelopes, which will be selected by an independent person from within the researchers' institute. Randomisation will occur after baseline data collection with the children.
The school participants (principal, teachers and classroom assistants) and parents/guardians in the two intervention groups will be blinded to their group allocation. Blinding of the health professionals to the schools' allocation will not be possible as the teams will inevitably know which intervention they are delivering. The risk of this influencing the outcomes will be minimised by the blinding of the research assistant (RA) who will be collecting the outcomes data.
The experimental RECALL and active control interventions both incorporate small group and whole-class activities designed to be fun for young children. The programmes are comparable in their structure, format and dosage (intervention frequency and duration). They consist of six, 40-minute sessions that are repeated three times per week for 6 weeks (18 sessions in total). The first session each week will be delivered by the health professionals who will model the activities for the teachers so that they can deliver the two further practice sessions.
The experimental RECALL programme is a theoretically underpinned, multi-component, manualised intervention that explicitly targets working memory (WM) skills. WM is the ability to hold in mind and mentally manipulate information for short periods of time in the face of distraction. RECALL incorporates evidence-based tasks that are all executive-loaded in nature i. e., the tasks require attentional and processing resources under executive control (not just the simple storage of information). The intervention tasks include: direct, complex WM training; cognitively-demanding physical activity; phoneme awareness training; fantastical play; and games targeting inhibitory control.

The active control intervention does not explicitly target WM and is not underpinned by WM theory. It aims to improve children's attention and listening skills through repeated practice at listening tasks. It focuses on teaching children the importance of listening and on the use of visual, verbal and behavioural strategies to support listening e.g., proximal praise. The tasks do not require the children to recall verbal or visuospatial information and they are not all executive-loaded.
To enhance the implementation of RECALL, the health professionals, who will be modelling the programme each week for the teachers, will attend a two-day training course prior to delivering it. To monitor compliance with the programme delivery and dosage, the health professionals and teachers will be asked to keep a simple log of their implementation (e.g., how often they delivered the programme and how long for). To monitor fidelity, three RECALL sessions in each school (one delivered by the health professional team and two by the teacher) will be observed by the research team.
There will be a 3 month follow-up period, at the end of which WM, attention and language skills will be assessed again.

Intervention Type
Behavioural

Primary outcome measure
Acceptability of RECALL in the school setting and feasibility of the trial processes, gathered throughout the trial and analysed in a process evaluation at the end of the study:
1. Compliance, assessed using implementation logs of the frequency and duration of programme delivery and recording of any reasons for non-delivery or modifications
2. Fidelity, assessed using 3 RECALL sessions in each school (1 delivered by the health professional team and 2 by the teacher), which will be observed by the first author. One of the health professional sessions and one of the teacher-delivered sessions will be observed simultaneously by a second member of the research team who will independently rate the delivery. Agreement between the raters will be checked by a third member of the team.
3. Acceptability, assessed using qualitative data on the health professionals' and teachers' experience of delivering RECALL, obtained in semi-structured interviews at the end of the study
4. Recruitment, consent and sampling procedures, assessed using the following:
4.1. Number and proportion of schools that meet the eligibility criteria
4.2. Number of schools approached
4.3. Number of schools where consent is obtained from principals and teachers
4.4. Number and proportion of children identified by teachers in each of the 3 sub-groups
4.5. Number and proportion of parents who consent
5. Attendance levels and loss to follow-up, assessed using the following:
5.1. Number of completed interventions
5.2. Number of completed standardised assessments, teacher rating scales and parent rating scales at post-intervention and three-month follow-up.
6. Acceptability of randomisation, assessed using the following:
6.1. Consent rates
6.2. Reasons given for participation and non-participation by school prinicipals
6.3. Qualitative data gathered in the semi-structured interviews, which will explore teacher's perspectives on random allocation
7. Acceptability of active control intervention as a comparator to RECALL, assessed using the following:
7.1. Health professionals' perspectives on similarities/differences between the programmes, explored in the semi-structured interviews
7.2. Observations of delivery by research team

8. Exploration of education as usual: semi-structured interviews will be conducted with teachers in the no-intervention (education as usual) control arm of the study to explore the activities and strategies they have employed to support children's attention and language skills during the intervention period
9. Acceptability of outcome measures for the children, teachers and RISE teams, assessed using the following:
9.1. Number of completed assessments for each child at each time point
9.2. Number lost to follow-up and reasons why if possible
9.3. Qualitative data obtained in semi-structured interviews
10. Unexpected adverse effects, recorded by the health professionals and teachers
11. Whether blinding is maintained at end of study, investigated in the semi-structured interviews

Secondary outcome measures

Current:
Children's working memory, attention and language skills, assessed pre-intervention, post-intervention and at the 3 month follow-up) using the following:
1. Standardised assessments administered directly with the children by a trained research assistant (RA) who will be blinded to group allocation. The children will be withdrawn individually from their classroom for approximately 1 hour at each time point to complete the following three standardised assessments:
1.1. The Automated Working Memory Assessment (AWMA), used to assess working memory
1.2. NEPSY – A Developmental Neuropsychological Assessment (NEPSY), used to assess attention
1.3. The New Reynell Developmental Language Scales (NRDLS), used to assess language skills
2. A teacher rating scale of the child's attention in the classroom, assessed using the The Behavior Rating Inventory of Executive Function-Preschool Version (BRIEF-P)
3. A parent rating scale of the child's language and communication skills at home, assessed using the The Focus on Communication Outcomes Under Six (FOCUS)
4. Weekly monitoring of the child's performance on the trained tasks by the health professionals using a pro-forma provided by the research team

Previous:
Children's working memory, attention and language skills, assessed pre-intervention, post-intervention and at the 3 month follow-up) using the following:
1. Standardised assessments administered directly with the children by a trained research assistant (RA) who will be blinded to group allocation. The children will be withdrawn individually from their classroom for approximately 1 hour at each time point to complete the following three standardised assessments:
1.1. The Automated Working Memory Assessment (AWMA), used to assess working memory
1.2. NEPSY – A Developmental Neuropsychological Assessment (NEPSY), used to assess attention
1.3. Clinical Evaluation of Language Fundamentals-Preschool, Second Edition (CELF-P2), used to assess language skills
2. A teacher rating scale of the child's attention in the classroom, assessed using the The Strengths and Difficulties Questionnaire (SDQ)
3. A parent rating scale of the child's language and communication skills at home, assessed using the The Focus on Communication Outcomes Under Six (FOCUS)
4. Weekly monitoring of the child's performance on the trained tasks by the health professionals using a pro-forma provided by the research team

Overall study start date

15/01/2018

Completion date
30/06/2019

Eligibility

Key inclusion criteria
Schools:
1. Situated in areas of low socio-economic status
2. Requested support from school-based therapy teams in relation to children's attention and language skills

Education staff (teachers and classroom assistants):
1. Work with year one classes (4-5 year olds) in a school that meets the above criteria.

Health professionals:
1. Work in school-based teams in the two participating HSCT areas
2. Speech and language therapists, occupational therapists, physiotherapists, or behaviour specialists with experience in delivering whole-class programmes

Children:
1. Be in a year one class, aged 4–5 years, in a school that meets the above criteria. They may have diagnosed or undiagnosed learning or developmental difficulties.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
At the cluster level, six schools will be recruited. One class of children in year one (n= ~30), their teacher and classroom assistant will participate in each cluster. A sample of 10 children in each class will be recruited to complete the outcome measures (n= 60). Health professionals (n= 4-8) will be recruited to deliver the experimental and active control interventions.

Key exclusion criteria
Schools:
1. No separate year one class i.e. if all year one children are taught within a composite class with older/younger children

Education staff (teachers and classroom assistants):
1. Previously accessed the active control intervention

Health professionals:
1. Work in a team that was involved in the co-production of RECALL

Children:
1. English is not their first language

Date of first enrolment
12/12/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Northern Health and Social Care Trust
Research Office
Research and Development Office
Bush House
Antrim Area Hospital
Bush Road
Antrim
United Kingdom
BT41 2QB

Study participating centre
Western Health and Social Care Trust
Research and Development Office
Clinical Translational Research & Innovation Centre (C-TRIC)
Altnagelvin Area Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Sponsor information

Organisation
Ulster University

Sponsor details
Research and Innovation,
Room 01H12,
Ulster University,

Jordanstown Campus
Shore Road
Northern Ireland
United Kingdom
BT37 0QB

Sponsor type
University/education

Website
ulster.ac.uk

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Not defined

Funder Name
Research and Development Division of the Public Health Agency, Northern Ireland

Results and Publications

Publication and dissemination plan
The findings will be disseminated to all of the participants at a local level through informal networks in the first instance. The results will be disseminated through conferences and publication in professional literature and international, peer-reviewed journals.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the feasibility nature of this study. However, any requests for data or material should be made to the corresponding author and requests will be reviewed by the Trial Steering Committee.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/06/2020	16/06/2020	No	No

Results article	results	06/02/2021	09/02/2021	Yes	No
Protocol article		24/06/2019	11/10/2023	Yes	No