Impact of skill and goal-based training in adults with dyslexia

Submission date 13/03/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered
		[ ] Protocol
Registration date 20/03/2023	**Overall study status** Completed	[ ] Statistical analysis plan
		[ ] Results
Last Edited 17/03/2023	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data
		[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
While reading and spelling are acquired seemingly effortlessly by most individuals, individuals with developmental dyslexia face lifelong challenges with these skills. For the most part, remediation approaches in children consist of skill-based training (i.e., targeting reading and writing skills) but these approaches don't show the same magnitude of effect in adults. Another intervention program, known as goal-based training, consists of the collaborative generation of psycho-social-based goals and strategies with reading rehabilitation experts. The aim of this study is to assess the impact of skill and goal-based training on brain activation.

Who can participate?
Adults with dyslexia

What does the study involve?
Participants are randomly allocated into the two programs to take part in an 8-week-long training program. Participants are asked to come to the lab for the pre-intervention (in-person) data collection session. The session consists of 40 minutes of behavioural testing and an hour of neuroimaging testing. During the neuroimaging session, participants are fitted with a cap. Each participant completes the phoneme deletion and sentence comprehension task while their brain activity is recorded. Both tasks are counterbalanced for all participants. After the tasks are done, participants are given information about the training program. After the training program is completed, participants return to the lab to complete the two tasks (with different stimuli).

What are the possible benefits and risks of participating?
There are no benefits to participants but there are scientific and social benefits. The results from this work have the potential to enhance social well-being, including mental health, social connectedness, and job success, for people with written communication difficulties. There are minimal risks like fatigue and COVID-19 exposure. To mitigate this, participants were allowed breaks to avoid fatigue. A detailed return-to-campus plan was drafted and followed diligently to avoid exposure.

Where is the study run from?
University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
January 2021 to February 2023

Who is funding the study?
Natural Sciences and Engineering Research Council of Canada (NSERC)

Who is the main contact?
Kulpreet Cheema, kulpreet@ualberta.ca

Contact information

Type(s)
Scientific

Contact name
Ms Kulpreet Cheema

Contact details
2-70, 8205 114 St Corbett Hall
Edmonton
Canada
T6G 2G4
+1 (0)7802931261
kulpreet@ualberta.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Pro00110746

Study information

Scientific Title
Neural impact of skill and goal-based training in adults with dyslexia

Acronym
NISGTD

Study objectives
The researchers wanted to examine the impact of skill and goal-based training on brain outcomes in adults with dyslexia. They expected training-related changes in brain networks

associated with literacy (superior temporal gyrus and inferior parietal lobule), self-referential processing (medial prefrontal cortex) and emotional regulation (dorsolateral prefrontal cortex) in both training groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2021, The University of Alberta Research Ethics Board (116 St & 85 Ave, Edmonton, AB T6G 2R3, Canada; +1 (0)780 492 0459; arise@ualberta.ca), ref: Pro 00110746

Study design
Intervention single-blinded randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Learning difficulties in adults with dyslexia

Interventions
All participants were randomly assigned to the two treatment groups of skill and goal-based training by a random number generator. Both groups were comparable in age, gender, years of education and years of dyslexia-related training

Skill-based training program:
For the SKILL-based group, participants were given access to the online training platform (https://www.rehabscience.com/literacy). This training targeted the four foundational skills of reading-sound awareness, print awareness, semantic/meaning awareness and fluency (Eden et al., 2004). In the sound awareness module, participants were trained on the identification and knowledge of sound patterns in English. The next component was the print awareness module which will include teaching the basic letter/spelling patterns in English. This was followed by the semantic/meaning awareness section, which included training on identifying and manipulating the meaningful units (called morphemes) for reading and spelling purposes. In addition to watching the video lessons, participants also completed assignments that will test their knowledge of the video content. The participant worked on each module for 2 weeks.
Lastly, participants completed the reading acceleration training to train their reading fluency skills. In this module, a series of sentences were presented on the screen and the letters started to disappear letter-by-letter in the direction of reading (left to right in this study). The letter erasure rate was decided based on the subject's performance on a set of 12 sentences. Weekly check-in meetings were conducted with the participants to answer any of their questions about the training/learning platform.

Goal-based training:
Participants in this training program completed an additional outcome measure of goal attainment scaling. In goal attainment scaling, participants were asked to come up with four goals that are most relevant to their condition/situation. Each goal was then rated on five outcome levels that range from the best expected, much better, slightly better and 'worse than

current' outcomes.
Following the goal setting, a detailed plan to work on each goal will be developed with the participant and a team of reading-rehabilitation experts in the lab. This included strategies and activities that the participant engaged in for 2 weeks to work towards their goals. After 2 weeks, goal attainment scaling was used to evaluate the level of attainment on the 5 outcome levels. The same process was repeated for each goal, and each goal was targeted for 2 weeks. The goal attainment scaling sessions were recorded (both video and audio recording with the participant's consent).

Intervention Type
Behavioural

Primary outcome(s)
Mean oxygenated hemoglobin concentration of specific brain regions measured with a Brite24 Artinis device at baseline and post-intervention (after 2 months)

Key secondary outcome(s))
Awareness of sounds and reading comprehension skills (mean accuracy and mean reaction time) measured with a Phoneme Deletion task and Sentence Comprehension task, respectively, at baseline and post-intervention (after 2 months)

Completion date
27/02/2023

Eligibility

Key inclusion criteria
1. English as the native or primary language
2. A standardized score of at least 1.5 SD below on at least one of the standardized reading measures
3. Score of at or above 0.70 on the Adult Reading History Questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
27

Key exclusion criteria
History of hearing or vision impairment and a diagnosis of neurological disorders like stroke

Date of first enrolment

15/10/2021

Date of final enrolment

20/11/2021

Locations

Countries of recruitment

Canada

Study participating centre
University of Alberta

116 St & 85 Ave
Edmonton
Canada
T6G 2R3

Sponsor information

Organisation

University of Alberta

ROR

https://ror.org/0160cpw27

Funder(s)

Funder type

Research council

Funder Name

Natural Sciences and Engineering Research Council of Canada

Alternative Name(s)

Conseil de Recherches en Sciences Naturelles et en Génie du Canada, The Natural Sciences and Engineering Research Council of Canada, nserc_crsng, NSERC, CRSNG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are not expected to be made available. Data is available upon reasonable request from Kulpreet Cheema (kulpreet@ualberta. ca). An anonymized and aggregated data file consisting of behavioral and functional near-infrared spectroscopy (fNIRS)-derived brain activation measures can be made available. If approved, data will be available from April 2023. Participant consent has been obtained.

IPD sharing plan summary
Available on request