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How effective is the World Health Organization's "Caregiver Skills Training programme"?

Submission date
09/11/2021

Recruitment status
No longer recruiting

Registration date
19/11/2021

Overall study status
Completed

Last Edited
24/04/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Autism spectrum disorder (ASD) is a condition related to brain development that impacts how a person perceives and socializes with others, causing problems in social interaction and communication. The disorder also includes limited and repetitive patterns of behavior. Caregiver-mediated interventions can potentially be effective for families who have a child with autism or related conditions. However, how well these programs work is still unknown. We are interested in assessing the effect of one such caregiver-mediated programme called the Caregiver's Skills Training (CST) program.
We aim to examine the extent to which the Canadian Skills Training (CST) programme trial can be feasibly implemented in rural and minority populations in Canada. Our secondary goal will also be to examine the effects of CST on caregiver-child interactions. Specifically, we hypothesize that parent-child interactions measures, namely synchrony and child initiated communication, will improve in the CST group but not in the control group, as the result of the intervention. Finally, we aim to examine the outcomes of implementing the intervention programme.

Who can participate?
A participant is eligible for the study if they satisfy the following criteria:
1. The child is aged between 2 to 7 years; 11 months,
2. The child is suspected of or diagnosed with ASD, a global developmental delay, an intellectual disability, or any other related neurodevelopmental condition,
3. The child is either pre-verbal or has language abilities that are lower than what is expected for their age, i.e., no more than 3-words in length.
4. The primary caregiver, i.e., the individual responsible for the daily care and upbringing of the child, including parents, grandparents or any other adult over the age of 18, is able to attend all relevant assessment and intervention activities.

What does this study involve?
The CST programme is an intervention programme delivered to parents by trained team members: a "Master Trainer" and a "Facilitator".

The programme consists of three components.
a) Group sessions: Caregivers are invited to participate in nine virtual group sessions every week, with up to 15 other caregivers via a videoconferencing platform, “Zoom”. Each session will last between two and three hours. During these sessions, caregivers will be taught strategies to promote communication, shared engagement, social skills and positive behaviours through play and home routines.
b) Virtual Home Visits: Our Facilitators will conduct three Virtual Home Visits in total via Zoom. The Virtual Home Visits are meant to help caregivers practice the strategies you learned from the programme with their child at home. Each Virtual Home Visit will last approximately 1.5 hours. As part of these Virtual Home Visits, the child’s skills will also be assessed. The assessment is designed as games and activities for your child.
c) Telephone Calls: Master Trainers will also communicate with caregivers by telephone (15-minute calls) four times during the course of the programme. This call will help to ensure that strategies are being targeted at home and will also give caregivers the opportunity to ask questions and to discuss difficulties that they may be having in implementing the strategies.
All sessions and evaluations will be done virtually on a videoconferencing platform called Zoom™. Zoom™ is an online tool allowing video, voice, or text-based communication. Access to these sessions are only given to invited participants. All Zoom sessions are video- and audio-recorded by the research team to a local computer.
Caregivers will be asked to complete online questionnaires and participate in a short 10-minute assessment before starting the program and at 4-month follow-up.

What are the possible benefits and risks of participating?
The caregiver will be required to attend multiple sessions (assessment sessions, questionnaires, and group intervention sessions) and will be required to respond to several questionnaires. Consequently, this programme will require a time commitment from caregivers. There may be certain psychological or emotional risks involved with undergoing assessments or answering questionnaires. Furthermore, some participants may become overwhelmed with the time required to undergo the programme, the assessment or answer questionnaires/interviews. Some participants may find home visits distressing. There is also the potential for child fatigue and some child behavioural dysregulation with the implementation of new strategies by the caregiver. While efforts will be made to protect the participants’ privacy, the use of a videoconferencing platform to deliver the intervention and to collect data cannot guarantee complete security and confidentiality in the event of a confidentiality breach by outside parties. Finally, because the CST programme is delivered in a group setting, confidentiality of participation cannot be guaranteed among participants assigned to the same group.
Participation in this study may lead to the following benefits to participants:
1. The opportunity to learn strategies to support their children.
2. For families waiting for a diagnosis, the overlap of assessments with those usually done in routine diagnostic services offers the advantage of having a confirmed diagnosis or alternatively, additional clinical information that can facilitate access to other services as needed.
3. Participants will receive a research report outlining their child’s results during the assessments. These results may be helpful in supporting access to other services as needed.

Where is this study run from?
Montreal Neurological Institute, McGill University (Canada)

When is the study starting and how long is it expected to run for?
September 2020 to May 2025

Who is funding the study?
Public Health Agency of Canada
Canadian Institutes for Health Research (CIHR)

Who is the main contact?
Dr Mayada Elsabbagh (autism@mcgill.ca)

Study website
https://canadacst.ca/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IUSMD-20-05

Study information

Scientific Title
A feasibility randomised controlled trial on the efficacy of the WHO's "Caregiver Skills Training programme"

Acronym
WHO-CST Trial

Study objectives
The aim of this study is to assess the feasibility of conducting a full-scale randomized control trial investigating the effectiveness of the Caregiver Skills Training (CST) programme to improve communication skills in children with autism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2021, Douglas Mental Health University Institute (6875 Boulevard LaSalle, Montreal, QC H4H 1R3, Canada; 514-761-6131; cer.reb@douglas.mcgill.ca) ref: IUSMD-20-05

Study design
Multi-site single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
https://canadacst.ca/

Health condition(s) or problem(s) studied
Communication skills intervention in children suspected of or diagnosed with ASD, a global developmental delay, an intellectual disability, or any other related neurodevelopmental condition.

Interventions
After screening and initial contact, eligibility will be assessed and informed consent will be obtained. Eligible participating families will complete baseline measures relating to communication and autism severity. Caregiver-child dyads will be randomly allocated to either the CST (n = 15 families) or to the control group (n = 15 families per group) with a 1:1 ratio and stratified by preferred language (English vs. French). A total of 60 families will be recruited. The control group will continue with treatment as usual at enrolment. The control group will receive access to an interactive website where the CST Participant Booklet is hosted.

The CST programme is a caregiver-mediated intervention model delivered through group meetings led by two interventionists i.e. a Master Trainer and a Facilitator. Master Trainers are professionals experienced in intervention delivery. Facilitators can be front line and/or community professionals trained and continually supported by the Master Trainer.

CST consists of three components:
a) Group Sessions: Consist of nine two-hour weekly group sessions led virtually by a Master Trainer and a Facilitator.
b) Individual Virtual Home Visits: Three Individual Virtual Home Visits will be completed over the course of intervention. This first Virtual Home Visit will take place within four weeks of the first Group Session, the second Virtual Home Visit between Group Sessions 3 and 5, and the final Virtual Home Visit within four weeks following the last Group Session. During these sessions the interventionists will follow a manualized intervention that focuses on establishing social engagement and language skills, and on diminishing challenging behaviours.
c) Telephone Calls: Master Trainers and Facilitators will also communicate with caregivers individually by telephone (10 -15-minute calls) four times during the course of the intervention. These calls will help to ensure that strategies are being targeted at home (i.e., implementation). Parents will also be given the opportunity to ask questions and to discuss any difficulties that they are having in implementing the strategies. In addition, these telephone calls will help increase communication between facilitators and caregivers, thus improving retention.

Intervention Type
Behavioural

Primary outcome measure
Measured at the end of the study:
1. Recruitment rates measured by recording the number of participants who consent to take part in the study.
2. Attrition rate is assessed by recording the percentage of participants in each arm of the study who fail to remain in the study until the last data collection point.
3. Completeness and adequacy of data collected will be assessed by recording the percentage of each of the measures that are fully completed by study participants.

Secondary outcome measures
1. Caregiver-child interaction measured using structured coding of a 10-minute free-play interaction at baseline and 4-month follow up
2. Caregiver distress measured by the distress thermometer at baseline and 4-month follow-up
3. Caregiver empowerment measured by the Family Empowerment Scale at baseline and 4-month follow-up
4. Child behavior and emotional problems and global impairment measured by the Strengths & Difficulties Questionnaire at baseline and 4-month follow up
5. Child language abilities by the MacArthur Communicative Development Inventories at baseline and 4-month follow up

Overall study start date
01/09/2020

Completion date
06/05/2025

Eligibility

Key inclusion criteria
1. The child is aged between 2 to 7 years; 11 months,
2. The child is suspected of or diagnosed with ASD, a global developmental delay, an intellectual disability, or any other related neurodevelopmental condition,

3. The child is either pre-verbal or has language abilities that are lower than what is expected for their age, i.e., no more than 3-words in length.
4. The primary caregiver, i.e., the individual responsible for the daily care and upbringing of the child, including parents, grandparents or any other adult over the age of 18, is able to attend all relevant assessment and intervention activities.

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
2 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Child is already enrolled in an intensive treatment program (more than 14 hours a week)
2. Any factor interfering with the caregiver's ability to complete the program; for example, limited knowledge of English; limited or unstable contact with the child; no access to a computer, tablet or laptop, or a secure internet connection.

Date of first enrolment
09/09/2021

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Canada

Study participating centre
Autism Yukon
108 Copper Rd
Whitehorse
Canada
Y1A 2Z6

Study participating centre
Autism Services of Saskatoon
209 Fairmont Dr
Saskatoon
Canada
S7M 5B8

Sponsor information

Organisation
Public Health Agency of Canada

Sponsor details
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+1-844-280-5020
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Sponsor type
Government

Website
https://www.canada.ca/en/public-health.html

ROR
https://ror.org/023xf2a37

Organisation
Canadian Institutes of Health Research

Sponsor details
160 Elgin Street
9th Floor
Ottawa
Canada
K1A 0W9
+1 613-941-2672
support-soutien@cihr-irsc.gc.ca

Sponsor type
Government

Website
https://cihr-irsc.gc.ca/e/193.html

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Public Health Agency of Canada

Alternative Name(s)
Agence de la Santé Publique du Canada, L'Agence de la santé publique du Canada, PHAC, ASPC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analysed during the current study will be available from the corresponding author on reasonable request.
Participant level data will be stored in a private, secure repository and access requests to anonymized data can be made to the PI Dr. Mayada Elsabbagh (Mayada.Elsabbagh@mcgill.ca) and approved by institutional REB

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		09/12/2024	22/04/2025	No	No