ISRCTN11702408 https://doi.org/10.1186/ISRCTN11702408

Pilot randomized controlled trial of the “WHO Parent Skills Training Programme for Caregivers of a Child with a Developmental Disorder”: Italian trial

Submission date
19/10/2022

Recruitment status
No longer recruiting

Registration date
01/11/2022

Overall study status
Completed

Last Edited
24/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) and international partners have developed a Caregiver Skills Training (CST) for caregivers of 2 to 9-year-old children with developmental disorders that can be implemented with low resources. The evidence-based WHO CST teaches strategies to engage children in communication and play and promote adaptive behaviours and learning. Before the programme can be scaled up, the CST needs testing in low- as well as high-income countries.

This study is expected to generate evidence on the effectiveness, acceptability and feasibility of a scalable sustainable training programme for caregivers of children with developmental disorders, including autism, in a public health setting in both rural and urban contexts in Italy. The lessons learned can be applied when implementing CST in other high-income countries.

With this research, we aim to collect data on the effectiveness of this new intervention package and its feasibility in a National Children's Health Service of Child Neuropsychiatry in Italy. This will help researchers to improve, if necessary, the intervention package and identify the best way to contribute to the diffusion of this intervention in the Italian National Health Service. We expect that the intervention works on child outcomes through the uptake of improved interaction strategies in the caregiver.

Who can participate?
Children between the ages of 2 and 5 years old with a clinical diagnosis of Autism Spectrum Disorder and their parents and legal guardians (caregivers)

What does the study involve?
Participants will be asked to sign an informed consent form before the study begins. Caregivers can attend research activities with your child. The research phases (from 1 to 5) are described below. Caregivers will be free to leave the studio at any time, for any reason.

Phase 1: Baseline assessments
All the research participants, children and caregivers, will be invited to the initial evaluation activities visit. Caregivers will be asked to complete some questionnaires and answer some clinical interviews concerning their child and themselves. Some structured assessments will be completed with your child to evaluate social-communicative skills, language, and developmental levels. Caregivers will be asked to play with their child with some toys. A timetable will be agreed upon for participation in these activities, which will take place at the local Child Neuropsychiatry service. Alternatively, if desired, they can be carried out at home.

Phase 2: Random assignment for the trial
After initial evaluations, through a code generated automatically by a computer at the Department of Psychology of the University of Turin, each participant will be randomly assigned to one of the following two groups:
1. Experimental group
2. Control group

Phase 3: Trial
During the experimentation phase, which will last about 3 months, the activities will be defined as follows:
1. The experimental group will receive the intervention WHO CST at the Child Neuropsychiatry service, in addition to the usual care at the same service
2. The control group will continue to receive regular care at the Child Neuropsychiatry Service

Phase 4: End-point assessment
Following the experimentation phase, all the research participants will be invited to the final evaluation activities. At this stage, caregivers will be invited back together with their child for a visit. As for the initial evaluations, there will be some questionnaires to complete and some clinical interviews concerning caregivers and their children will be undertaken. Structured assessments will be completed with your child to evaluate social-communicative skills, and language and the caregiver will be asked to play with their child with some toys.

Phase 5: Follow-up assessments
About 3 months after the final evaluations, there will be a final invite to a research visit. During this phase, a reduced version of the questionnaires and clinical interviews will be completed, and some structured assessments with the child will be undertaken. The caregiver will be asked to play with their child with some toys.

What are the possible benefits and risks of participating?
There are no direct specific benefits arising from participation in the research. However, the information and data we can obtain from these studies will allow us to better understand how to make an intervention for parents of children with Autism Spectrum Disorder effective. Our hypothesis is that participation in the WHO intervention can improve caregiver well-being and child development. To validate this hypothesis we are conducting this effectiveness study. At the end of the research activities, a group meeting will be held where the results will be presented and the team will discuss the implications for clinical psychology. It will be clear to all the participants from the outset of the study that there are no direct benefits of taking part in the study, except for the receipt of the intervention for which the available preliminary evidence indicates good acceptability. A refund will be offered for each visit to support the costs of transport from home to the venue of the assessments (clinics). Drinks and snacks will be provided for families. All children will receive a small gift at the end of each assessment visit. Families will receive a brief report summarizing the results of the assessments.

There are limited disadvantages or risks that could be incurred by participating in the research activities. Regarding activities with the child, all materials and toys used have been tested and are safe for handling and use by preschoolers. The research activities consist of semi-structured games and development tests, frequently used in research internationally and also in clinical practice, and generally appreciated by children. The interviews and questionnaires are also frequently used in international research and are generally welcome by parents. However, if at any time the caregiver or child should not like the activities, or does not want to answer some questions, it will be possible to suspend the participation temporarily or permanently. Any aspect of the research can be discussed with the staff of the Child Neuropsychiatry Service and the researchers. Since the WHO intervention is based on principles derived from evidence-based interventions, no risks from participation in the intervention are expected. At any time, caregivers will have the opportunity to discuss with the staff of Child Neuropsychiatry or the Department of Psychology any aspect that they want to further explore.

Where is the study run from?
University of Turin (Italy)

When is the study starting and how long is it expected to run for?
April 2016 to May 2018

Who is funding the study?
European Union’s Seventh Framework Programme for research and innovation under the Marie Skłodowska-Curie grant agreement (Italy)
Compagnia di San Paolo Foundation (Italy)

Who is the main contact?
Prof Erica Salomone
erica.salomone@unimib.it

Contact information

Type(s)
Principal investigator

Contact name
Prof Erica Salomone

ORCID ID
https://orcid.org/0000-0002-8083-5942

Contact details
Piazza dell'Ateneo Nuovo 1
Milano
Italy
20126
+39 02 6448 3816
erica.salomone@unimib.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 1, 30/04/2016

Study information

Scientific Title
Pilot randomized controlled trial of the “WHO Parent Skills Training Programme for Caregivers of a Child with a Developmental Disorder”: Italian trial

Acronym
CST-ITA

Study objectives
The addition of WHO Caregiver Skills Training (CST; formerly called: WHO Parent Skills Training, PST) to treatment as usual (TAU) in children with autism spectrum disorder (ASD) improves child and caregiver outcomes more than TAU .

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/06/2016, Ethics Commitee 'Comitato Etico Interaziendale A.O.U. San Luigi Gonzaga di Orbassano ASL TO2 (Torino)' (Regione Gonzole 10, 10043 Orbassano, Turin, Italy; +390119026566204; sperimentazioni@sanluigi.piemonte.it), ref: 0010244; n. 88/2016

2. Approved 20/09/2016, Ethics Commitee 'Comitato Etico Interaziendale A.O.SS. Antonio e Biagio e Cesare Arrigo - Alessandria' (Via Venezia 16, 15121 Alessandria, Italy; +390131206111; info@ospedale.al.it), ref: 0019903; n. AslAL.NPI.16.01

3. Approved 14/12/2016, Ethics Commitee 'Comitato Etico Interaziendale A.S.O. Santa Croce e Carle di Cuneo, AA.SS.LL. Cuneo 1, Cuneo 2, Asti (Via Monte Zovetto 18, 12100 Cuneo, Italy; +390171641571; comitato.etico@ospedale.cuneo.it), ref: 180-16 ASLCN1/PSIC.2

4. Approved 07/08/2017, Ethics Commitee 'Comitato Etico Interaziendale A.S.U. Città della Salute e della Scienza di Torino - A.O. Ordine Mauriziano di Torino - A.S.L. Città di Torino (Corso Bramante 88/90 – 10126 Torino, Italy; +390116334171; comitatoetico@cittadellasalute.to.it), ref: 007761; n. CS2/354

Study design
Two-arm single-(assessor)-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions
Following baseline ascertainment, participants, identified by sequentially assigned identification numbers, were randomly assigned by an independent statistician to either CST (n = 43) or eTAU (n = 43) on a 1:1 allocation ratio using stratified randomization by age (below 42 months and 42 months and above) and autism severity (ADOS-2 Comparative Severity Score: minimal/low and moderate/high algorithm categorizations). These characteristics were selected as factors that may influence the treatment response. Allocation was conveyed by email to the site coordinator who relayed it to the intervention team. The research and intervention teams used separate office facilities. Research assistants, who were masked to treatment allocation, rated baseline, immediate post-intervention and 3-months post intervention measures from anonymized video-recordings without indication of arm or timepoint.

Caregiver Skills Training (CST):
The Caregiver Skills Training (CST) is a group intervention developed by the World Health Organization [Caregiver skills training for families of children with developmental delays or disabilities: introduction. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.]
The 12-sessions CST intervention program includes 3 home visits and 9 group sessions training caregivers via adult-learning techniques (Salomone et al., 2019). The first Home Visit is aimed at goal setting and is conducted before the first group session, the second one focuses on coaching and occurs at the mid-point of the program; the third home visit delivers coaching and support for independent practice and occurs after the last group session. The group sessions cover the following topics: getting and keeping children engaged (Sessions 1-2); building home and play routines (Session 3); understanding and promoting communication (Sessions 4-5); preventing and reducing challenging behavior (Sessions 6-7); promoting daily living skills (Session 8); caregiver wellbeing and problem-solving (Session 9). Each session includes a wellness activity (breathing exercise), a review of the previous session and of home practice, a discussion of a caregiver story (illustrated clinical vignette), the presentation of new content with the aid of visuals, the demonstration (modelling) of intervention strategies, the caregiver role play and the guided plan for home practice. Caregivers are expected to practice independently at home with the intervention strategies; the home practice is reviewed during the group sessions.

Treatment as usual (TAU):
In line with standard practice for clinical trials in autism, access to normally provided services (TAU) will not be restricted in either group during the study. We will examine the amount and type of intervention services that the Experimental group children will receive during treatment and the Control group children will receive during the waitlist period in relation to the primary outcome measures at post-treatment and 3-months follow-up (controlling for pre-treatment scores).
In the Piedmont Region of Italy, TAU for children with autism in this age range predominantly consists of publicly provided occupational and speech and language therapy and generic psycho-education.; Additionally, families may choose to privately access autism-specific behavioural interventions.

Autism symptom severity:
The Brief Observation of Social Communication Change (BOSCC) is a measure of change in social communication behaviors developed based on ADOS-2 codes. The tool is under development; Version July 27, 2017 is used in this study. When applied to caregiver/child interaction, the BOSCC consists of 15 items rating the child's behavior: nine items consider social-communication skills (such as eye contact, gestures, social overtures), three items rate restricted and repetitive behaviors (including sensory interests, mannerisms and stereotyped behaviors) and the last three items describe behaviors not specifically associated with, but frequently occurring in, ASD (hyperactive, disruptive, and anxious behaviors). All items are coded on a 6-point scale (0 – abnormality is not present to 5 – abnormality is present and may significantly impair functioning) with the aid of a decision tree. Averaged scores are obtained for two 5-minutes segments that are scored separately. The "Total BOSCC" change score between baseline and 3-months post-intervention will be used in the analyses.

Dyadic engagement:
The Joint Engagement Rating Inventory (JERI; Adamson et al., 2020) is a measure designed to characterize various aspects of joint engagement that occurs as caregivers interact with typically developing toddlers between 18 and 30 months old and young children with developmental delays, including those diagnosed with ASD. The current version of the JERI contains 32 rating items that have been constructed as researchers have adapted the original set of rating items to suit specific studies; as recommended in the manual, the current study selected a subset of items germane to the research questions. Eight items are used: two engagement items – child joint engagement and child unengaged; two child behavioral items – initiation of communication, attention to the caregiver; three caregiver behavioral items – scaffolding, following in on the child's focus, effective communication; and one dyadic interaction item – fluency and connectedness. Items are scored on a 7-point rating scale (1 – feature is minimally present, 7 – feature is highly present). See Figure 1. Four variables were derived from the rating items to measure the constructs of joint engagement (one item: child joint engagement); child availability to interact (three items: reversed scored unengaged, attention to the caregiver, initiation of communication); parent support of interaction (three items: scaffolding, following in, effective communication): and flow of interaction (one item: fluency and connectedness). The "Joint Engagement", "Child Availability to Interact", "Parent Support of Interaction" and "Flow of the interaction" change scores between baseline and 3 months post-intervention will be used in the analyses.

Procedure to obtain the primary outcome measures:
The primary outcome measures are derived from a free play caregiver-child interaction with a standard toy kit suitable for a range of developmental play levels video recorded at baseline, immediately post-intervention and 3 months post-intervention, at the child's home. Parents are instructed to play as they would usually do. Ten consecutive minutes of an approximately 12-minute interaction were rated to obtain the primary outcome measures. Rating began when the dyad had settled and either the parent or child engaged with an object. Rating procedures were applied as per the manual for each measure by two observers (FF and GF), both clinical psychologists fluent in Italian and experienced in clinical work with young children with ASD. Raters achieved a high level of agreement with the master trainer (ES) before rating the video corpus. Prior to data coding, the master trainer trained the two raters until the recommended reliability standards were met; throughout data collection, the raters met with the master trainer to discuss ongoing reliability. Raters are blind to the study's hypotheses, group allocation and time point of the assessment. The video corpus is rated with the BOSCC first, and subsequently with the JERI.

Child vocabulary and gestures
The Italian version of the MacArthur-Bates Communicative Development Inventories (MCDI) is used to measure child vocabulary and gestures. The MCDI shows very high concurrent validity with direct assessments and the inter-rater reliability of parent and teacher ratings is excellent. Total endorsed receptive and expressive words raw counts (maximum possible score for each total: 408) and gestures raw counts (maximum possible score: 12) are used in the analysis. The "Total Receptive", "Total expressive" and "Total Gestures" change scores between baseline and 3 months post-intervention will be used in the analyses.
The Italian version of the Vineland II (VABS) is used to measure child adaptive behaviour. The Vineland is a semi-structured interview that rates the child's current level of functioning across the domains of Communication, Daily Living and Socialization. Age-normed Standard Scores (M = 100; SD = 15) for the Adaptive Behavior Composite (ABC) are used in analyses. The ABC change score between baseline and 3-months post-intervention will be used in the analyses.

Parenting self-efficacy
Parenting self-efficacy is assessed with a general measure of parenting satisfaction and efficacy, the 17-item self-report Parenting Sense of Competence Scale (PSOC) and the Caregiver Self-efficacy Questionnaire, (CSQ, included in the WHO Caregiver Knowledge and Skills Test, WHO, unpublished), a 13-item 5-point scale measure of parenting self-efficacy applied to domains relevant for parenting a child with developmental delay (e.g. promoting skills development, inclusion, coping with challenging behavior). The PSOC has good internal reliability ($\alpha = 0.75–0.88$, Johnston & Mash, 1989; Lovejoy et al., 1997), but an uncertain factor structure. The "Total PSOC" and "Total CSQ" change scores between baseline and 3 months post-intervention will be used in the analyses.

Parental stress:
Parental stress is measured with an autism-specific questionnaire, the Autism Parent Stress Index (APSI, Silva & Schalock, 2012). The APSI is a 13-item self-report questionnaire examining parenting stress related to a child's ASD core deficits, behavioral symptoms, and co-morbid physical symptoms. It showed adequate internal reliability in ASD parents (e.g. $\alpha = 0.67–0.83$), good test-retest reliability (e.g. $r = 0.88$), good discriminant validity among parents of children with ASD, DD, and typically developing children (Silva & Schalock, 2012). The "Total APSI" change score between baseline and 3 months post-intervention will be used in the analyses.

Intervention Type
Behavioural

Primary outcome(s)
1. Child autism symptom severity measured using the Brief Observation of Social Communication Change (BOSCC) total score at baseline and 3 months post-intervention
2. Child joint engagement measured using the Child Joint Engagement item of the Joint Engagement Rating Inventory (JERI) at baseline and 3 months post-intervention
3. Child availability to interact measured using the Child Availability to Interact (three items: reversed scored unengaged, attention to the caregiver, initiation of communication) of the JERI at baseline and 3 months post-intervention
4. Flow of the interaction measured using the Fluency and connectedness item of the JERI at baseline and 3 months post-intervention
5. Parent skills supportive of interaction measured using the Parent Support of Interaction (three items: scaffolding, following in, effective communication) of the JERI at baseline and 3 months post-intervention

Key secondary outcome(s))
1. Child expressive vocabulary measured using the Total Expressive Words raw counts on the Italian version of the MacArthur-Bates Communicative Development Inventories (MCDI) at baseline and 3 months post-intervention
2. Child receptive vocabulary measured using the Total Receptive Words raw counts on the Italian version of the MCDI at baseline and 3 months post-intervention
3. Child gestures measured using the Total Gestures raw counts on the Italian version of the MCDI at baseline and 3 months post-intervention
4. Child adaptive behaviour measured using the Adaptive Behavior Composite of the Vineland II (VABS) age-normed Standard Scores at baseline and 3 months post-intervention
5. Parenting satisfaction and self-efficacy measured using the Total Score of the Parenting Sense of Competence Scale (PSOC) at baseline and 3 months post-intervention
6. Parenting self-efficacy specific to the child with neurodevelopmental disorder measured using the Caregiver Self-efficacy Questionnaire (CSQ) total score at baseline and 3 months post-intervention
7. Parental stress specific to autism measured using the Autism Parent Stress Index (APSI) total score at baseline and 3 months post-intervention

Completion date
07/05/2018

Eligibility

Key inclusion criteria
1. Children aged between 24 and 59 months old and their parent(s)/guardian(s) or other caregivers
2. Recruited from Child Neuropsychiatry Services of the Italian National Health System
3. Clinical diagnosis of autism confirmed by research evaluation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
24 months

Upper age limit
59 months

Sex
All

Total final enrolment
86

Key exclusion criteria
For the parent:
1. Level of Italian speaking insufficient to fully participate in the intervention
2. Any record of a serious psychiatric disorder in the local clinical notes in the parent (such as to prevent the use of the intervention)

Date of first enrolment
01/09/2016

Date of final enrolment
12/10/2017

Locations

Countries of recruitment
Italy

Study participating centre
Azienda Sanitaria Locale "Città di Torino"
Via San Secondo 29
Torino
Italy
10128

Study participating centre
S.C. Neuropsichiatria Infantile Dipartimento "Materno Infantile" Novi Ligure
Via Papa Giovanni XXIII n.1
Novi Ligure (AL)
Italy
15067

Study participating centre
S.C. Neuropsichiatria Infantile Mondovì - Cuneo
Via San Rocchetto 99
Mondovì (CN)
Italy
12084

Sponsor information

Organisation

University of Turin

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Government

Funder Name
H2020 Marie Skłodowska-Curie Actions European Union’s Seventh Framework programme for research and innovation under the Marie Skłodowska-Curie grant agreement No 609402 - 2020 researchers: Train to Move (T2M)

Alternative Name(s)
H2020 Excellent Science - Marie Skłodowska-Curie Actions, Marie Skłodowska-Curie Actions, EXCELLENT SCIENCE - Marie Skłodowska-Curie Actions, Excellent Science: Marie Skłodowska-Curie Actions, H2020 ECCELLENZA SCIENTIFICA - Azioni Marie Skłodowska-Curie, ECCELLENZA SCIENTIFICA - Azioni Marie Skłodowska-Curie, Azioni Marie Skłodowska-Curie, Actions Marie Skłodowska-Curie, H2020 EXCELLENCE SCIENTIFIQUE - Actions Marie Skłodowska-Curie, EXCELLENCE SCIENTIFIQUE - Actions Marie Skłodowska-Curie, CIENCIA EXCELENTE - Acciones Marie Skłodowska-Curie, Acciones Marie Skłodowska-Curie, H2020 CIENCIA EXCELENTE - Acciones Marie Skłodowska-Curie, WISSENSCHAFTSEXZELLENZ- Marie Skłodowska-Curie Maßnahmen, Marie-Skłodowska-Curie-Maßnahmen, H2020 WISSENSCHAFTSEXZELLENZ- Marie Skłodowska-Curie Maßnahmen, MSCA, MSCM, AMSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Compagnia di San Paolo grant agreement Bando Intrecci 2016, No 2016.2208

Alternative Name(s)
San Paolo Company, San Paolo Company Foundation, Compagnia San Paolo, Fondazione Compagnia di San Paolo, CSP, FCSP

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
Italy

Results and Publications

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 lack of consent from participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/08/2021	19/10/2022	Yes	No
Results article		22/10/2021	19/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes