ISRCTN15312724 https://doi.org/10.1186/ISRCTN15312724

Tele-assisted behavioral intervention for families with children with autism spectrum disorders

Submission date
04/09/2020

Recruitment status
No longer recruiting

Registration date
14/09/2020

Overall study status
Completed

Last Edited
24/09/2020

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
Telehealth is the use of digital information and technology, such as computers and mobile devices, to access health care services remotely. Telehealth is useful for both autism spectrum disorder (ASD) diagnosis and treatment, but studies with a direct comparison between tele-therapy and traditional in-person therapy are limited.

Telehealth is useful for both ASD diagnosis and treatment, but studies with a direct comparison between tele-therapy and traditional in-person therapy are limited. Evidence-based treatments supported by parent-mediated interventions are crucial to obtain improvements in the developmental trajectories and functional outcomes of children with ASDs. Telehealth represents a new technology able to emphasize the strengths of current treatment methods, mainly because it offers: possible remote diagnostic methods so a possible reduction in the delay in ASD detection; continuous access to care for families with children with autism; and the chance to directly involve family members in the child's development by actively applying effective parent-mediated interventions.

This randomized control trial aims to compare the effect of a tele-assisted and inperson intervention based on a behavioral intervention protocol for families with children affected by ASDs.

Who can participate?
Parents of children with autism (aged 30 months to 10 years old)

What does the study involve?
Parents are randomly assigned to receive 12 sessions of an applied behavioral analysis (ABA) intervention implemented in an individual and group setting, either with or without the inclusion of tele-assistance. Assessments will be conducted using questionnaires before and after the intervention.

What are the possible benefits and risks of participating?
Telehealth may be beneficial as this new technology is able to apply and strengthen the current treatment methods. Clear advantages are a continuous, intensive, and ubiquitary access to care for families with children with autism and the chance to directly involve family members in the child's development by actively applying effective parent-mediated interventions. In the experience of the research team, as well as in literature, parents demonstrate high interest in web-based platforms, which increase the parents' collaboration, and therefore may further benefit their child.

Parent–child interactions are generally not influenced by computer, tablet, or general technology concerns, e.g., internet connection, digital divide, or anxiety regarding their performance when using technology. This is in line with the previous literature reporting how effective, acceptable, and usable ubiquitous communication technology is for the parents. In case of digital divide or difficulties, parents can return to use the traditional in-person treatment.

Where is the study run from?
Institute for Biomedical Research and Innovation (Italy)

When is the study starting and how long is it expected to run for?
From July 2018 to July 2020

Who is funding the study?
Project SIRENA - Sistemi Innovativi di Ricerca E-health per la Neuro-Abilitazione from Institute for Biomedical Research and Innovation (IRIB) National Research Council of Italy (CNR) (Italy)

Who is the main contact?
Dr Giovanni Pioggia
giovanni.pioggia@cnr.it

Contact information

Type(s)
Scientific

Contact name
Dr Giovanni Pioggia

ORCID ID
https://orcid.org/0000-0002-8089-7449

Contact details
via V. Leanza
Istituto Marino di Mortelle
Messina
Italy
98164
+39 3203390892
giovanni.pioggia@cnr.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TELE-001

Study information

Scientific Title
Tele-assisted behavioral intervention for families with children with autism spectrum disorders: a randomized control trial

Study objectives
We hypothesize that the parents of children on the autism spectrum randomly assigned to the tele-assisted intervention will perceive:
1. A decrease in the severity of disruptive and noncompliant behavior in their children after the intervention
2. That their children become easier to manage compared to children on the autism spectrum who undergo the intervention without telehealth assistance
3. Lower parental distress
4. Improvements in the parent–child functional interaction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/08/2018, the Research Ethics and Bioethics Committee of the National Research Council of Italy (CNR) (Via dei Taurini, 19, Rome 00185, Italy; +39 (0)6 4993/7900 - 7671; cnr. ethics@cnr.it), ref: CNR-AMMCEN 54444/2018

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Autism spectrum disorders (ASD)

Interventions
Families will be recruited as part of an ongoing research program. Parents will be randomly assigned to the intervention group (TG), the tele-assisted intervention, or to the control group (CG), applying exactly the same protocol without telehealth assistance. A randomized block design will be used to ensure that intervention groups were balanced with respect to gender,

age, and developmental quotient (DQ). The therapy will be based on applied behavioral analysis (ABA), a type of therapy that can improve social, communication, and learning skills through positive reinforcement.

The child psychologist will collect information from parents concerning developmental milestones (including joint attention, social interaction, pretend play, and repetitive behaviors, with an onset prior to 3 years of age) and current behaviors.

The protocol consists of three consecutive phases. In phase I, all of the enrolled parents receive 12 2-hour-long plenary sessions of informative parent training about ASD characteristics and ABA/behavioral principles. Phase II lasts 12 weeks, and all of the enrolled parents receive 2 h /week of group behavioral therapy administered in homogeneous groups (based on the developmental age, target behaviors, and ASD level of their children). In this phase, all of the children of the enrolled parents receive 1 hour/week of one-to-one ABA therapy, where parents were allowed and invited to observe the therapists during treatment sessions. Phase III lasts 12 weeks and consists of the administration of 2 h/week of tele-assisted one-to-one behavioral parent-training and coaching to participants belonging to the TG, while 2 h/week of in-person one-to-one behavioral parent-training and coaching was administered to participants belonging to the CG.

All of the therapies will be administered by a clinical psychologist with a post-Master's degree in behavioral modification and analysis. Considering the usual ABA protocols last 25-40 hours /week, this protocol can be considered to be low intensity. Testing the efficacy of low-intensity protocols, mediated by parents in natural environments, is of utmost importance to develop more efficient implementations.

The investigators who will assess the outcome measures will be blinded to intervention allocation.

Intervention Type
Behavioural

Primary outcome(s)
1. Perception and influence of children's behavior on the psychological state of their parents, Social Inflexibility (SI) and Demand-Specific (DS) measured using the Home Situation Questionnaire (HSQ-ASD) at baseline and 12 weeks
2. Parental Distress (PD); Parent–Child Dysfunctional Interaction (P–CDI), perception of the child as not responding to parental expectations; and Difficult Child (DC), which is centered on some of the characteristics of the child that make it easy or difficult to manage, are measured by the Parental Stress Index (PSI/SF) at baseline and 12 weeks

Key secondary outcome(s))
1. Observing whether challenging behaviour is occurring due to the method or technology, or to their child, or if a person is trying to communicate issues through their behaviour, assessed by direct observations of the parents by a chartered psychotherapist, well-experienced in working with children on the autism spectrum and parents between baseline and 12 weeks

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Parents of children aged between 30 months and 10 years
2. Children of the recruited families having a clinical diagnosis of an ASD based on the DSM-5 criteria from a licensed clinical child neuropsychiatric. All children must have a previous diagnosis that will be further confirmed through the assessment and the consensus of the experienced professionals on the research team (a child neuropsychiatrist and a clinical psychologist).
3. DSM-5 severity scores from moderate (level 2) to severe (level 3) in both the social communication and the restricted interests and repetitive behaviors domains

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
42

Key exclusion criteria
1. DSM-5 severity score level 1 in the social communication or the restricted interests and repetitive behaviors domains
2. Receiving psychiatric medication
3. Receiving any other intervention directly related to behavioral skills during the trial

Date of first enrolment
01/01/2020

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Italy

Study participating centre
Institute for Biomedical Research and Innovation
via V. Leanza
Istituto Marino di Mortelle
Messina
Italy
98164

Sponsor information

Organisation
Institute for Biomedical Research and Innovation (IRIB)

ROR
https://ror.org/05b170984

Funder(s)

Funder type
Government

Funder Name
Consiglio Nazionale delle Ricerche

Alternative Name(s)
National Research Council, Consiglio Nazionale delle Ricerche (IT), The National Research Council (Cnr), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
Data are anonymised. The study team will not store the personal data. All of the parents of the children who took part in the study gave their consent to participate in this study, signing a written consent form. The datasets generated and analysed during the current study during this study will be included in the subsequent results publication as supplementary materials.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	18/09/2020	24/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes