

Testing a culturally tailored online training program to help parents and caregivers manage challenging behaviors in autistic children at home

Submission date 07/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/09/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many children with autism experience challenging behaviors, such as tantrums and aggression, which can make daily life difficult and impact their ability to interact with others. These behaviors can also cause significant stress, anxiety, and depression in parents and caregivers. In Pakistan, around 400,000 children are affected by autism, and there are limited resources available to help families manage these challenges. This study aims to test a new training program for parents and caregivers of children with autism to help them better manage challenging behaviors. The program is designed to be delivered online (via telehealth) to make it accessible to families across Pakistan.

Who can participate?

Parents or primary caregivers of children aged 2 to 16 years who have been diagnosed with autism and have internet access for video conferencing can participate.

What does the study involve?

If you decide to participate, you will first be provided with detailed information about the study, including potential benefits and risks, and asked to give your consent. Then, all participants will complete an initial assessment. Participants will be randomly assigned to either a group receiving the online training program or a control group. After all sessions are completed, a follow-up assessment will be conducted to measure the impact of the training.

What are the possible benefits and risks of participating?

Since this is a behavioral training program, there are no expected risks or harms from participating. The possible benefits include learning new strategies to help manage your child's behaviors more effectively.

Where is the study run from?
Foundation University Islamabad
Pakistan Institute of Learning and Living

When is the study starting and how long is it expected to run for?
September 2022 to May 2025

Who is funding the study?
Higher Education Commission of Pakistan

Who is the main contact?
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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

NRPU 17141

Study information**Scientific Title**

A feasibility randomized controlled trial for evaluating the Culturally adapted Telehealth Empowering program for parents/caregivers to Address Challenging behaviors of autistic children at Home (C-TEACH)

Acronym

C-TEACH

Study objectives

A culturally adapted parent-mediated telehealth training will be feasible and acceptable to deliver among parents in Pakistan while improving the adaptive behaviors of their children, reducing parental burnout, and improving parental self-efficacy in parents of children with Autism in Pakistan.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/09/2022, Foundation University Islamabad (New Lalazar, Rawalpindi, 44000, Pakistan; +92 515151433; info.fusst@fui.edu.pk), ref: FURC/IRB/Spring-2022/48

Study design

Feasibility randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Challenging behaviors in children with autism

Interventions

All recruited participants who screen positive (Score on Aberrant behavior checklist-Irritability scale greater than 15) will be included after obtaining informed consent. They will be randomized into 2 groups through an online tool (computer generated randomization table)

Group 1 (Parent Intervention): This group will receive a Culturally Adapted Telehealth Parent-Mediated Training, which is based on the RUBI parent training manual to manage disruptive behaviours in children with Autism and includes an additional mindfulness component modified from Compassion focused therapy to address parental distress. This intervention will comprise of 12 sessions (each session lasting 90 minutes), delivered once a week in a group format, online. The focus will be on teaching the ABC model to parents, providing strategies to implement appropriate responses such as positive reinforcement, planned ignoring, and compliance training along with teaching essential life skills. The goals are improved adaptive skills and decreased maladaptive behaviors in children with Autism, and reduced parental burnout using Mindfulness based stress management.

Group 2 (Parent Education): The other group will receive parent education sessions (as the control group) in a group format once a week for 12 weeks. Each session will last for 90 minutes and focus on general principles of counselling related to care and behavioural management of children with Autism.

In both groups, the sessions will be conducted by relevant qualified professionals. Baseline assessments will be done pre intervention, followed by a final post intervention assessment at the end of 12 weeks.

Intervention Type

Behavioural

Primary outcome(s)

1. Challenging/Disruptive behaviors in children will be measured using the Aberrant Behavior Checklist irritability subscale at baseline and post-intervention
2. Non-compliant behaviors in children will be measured using the Home Situation Questionnaire at baseline and post-intervention
3. Overall intervention effectiveness will be assessed using the Clinical Global Impressions-Improvement Scale at baseline and post-intervention

Key secondary outcome(s)

1. Parental burnout will be assessed using Parental Burnout Assessment at baseline and post-intervention
2. Parental self-efficacy will be assessed using Autism Specific Self-efficacy scale at baseline and post intervention
3. Adaptive behaviors in children will be assessed using Adaptive Behavior Assessment System-3 at baseline and post-intervention
4. Treatment Fidelity Checklist (TFC) will be used to assess parental adherence to sessions of

training at each session

5. Telehealth Caregiver Satisfaction Survey to obtain parental feedback on the telehealth delivery of the PTDB program post-intervention

6. Parent Treatment Adherence Scale (PTAS) to assess adherence to session objectives post intervention

7. Parent Satisfaction Questionnaire for assessing parental satisfaction from training post-intervention

Completion date

31/05/2025

Eligibility

Key inclusion criteria

1. Parents of children aged 2-16 years with a diagnosis of Autism Spectrum Disorder

2. Behavioral difficulties measured as a score 15 or more on the Irritability sub-scale of Aberrant Behavior Checklist-Community (ABC-C)

3. Participant is a parent or primary caregiver of child

4. Having access to internet and an electronic device to attend online sessions

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

16 years

Sex

All

Key exclusion criteria

1. Any physical disability such as hearing impairment, blindness in parent

2. Any medical condition in parent like pregnancy or any chronic disease

3. Not having the resources to do video-conference calls

4. Parents who have received any intensive parent training during the past 12 months

Date of first enrolment

10/06/2024

Date of final enrolment

31/01/2025

Locations

Countries of recruitment

Pakistan

Study participating centre

Foundation University Medical College/ Fauji Foundation Hospital

DHA Phase 1

Islamabad

Pakistan

44000

Study participating centre

Pakistan Institute of Learning and Living, Pakistan

Institute of psychiatry, benazir bhutto hospital, murree road

Rawalpindi

Pakistan

46000

Sponsor information

Organisation

Foundation University Islamabad

ROR

<https://ror.org/0130a6s10>

Organisation

Pakistan Institute of Learning and Living

ROR

<https://ror.org/046aqw930>

Funder(s)

Funder type

Government

Funder Name

Higher Education Commision, Pakistan

Alternative Name(s)

Pakistani Higher Education Commission, Higher Education Commission of Pakistan, HEC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Pakistan

Results and Publications

Individual participant data (IPD) sharing plan

To ensure the scientific integrity of the study, participant data will not be shared or disclosed for publication or oral presentations before the trial concludes, unless authorized by the Principal Investigator. The full data-sharing plan will be made available at a later date.

IPD sharing plan summary

Stored in non-publicly available repository, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/01/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes