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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

Registration date
18/09/2024

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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?
Dr Nadia Shafique, nadiashafique17@gmail.com
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Study website
https://fautism.com/

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Internet/virtual

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
See outputs table

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 measure

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

Secondary outcome measures
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

Overall study start date
24/09/2022

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

Age group
Child

Lower age limit
2 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
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Research organisation

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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

Publication and dissemination plan
Upon the completion of the clinical trial, we will disseminate our findings through multiple channels to ensure broad reach and impact. We will host webinars to present general results, inviting stakeholders such as parents of children with autism and healthcare professionals to facilitate engagement and discussion. Additionally, we will submit our research findings for publication in a relevant peer-reviewed scientific journal to contribute to the academic community and ensure the results are accessible to researchers and practitioners. Authorship decisions for manuscripts submitted to medical journals will adhere to ICMJE guidelines. The research team will also present the findings at both national and international conferences. These events will be aimed at academics, healthcare professionals, and policymakers. This multi-faceted approach will help us maximize the visibility and application of our findings, ultimately benefiting those affected by autism and informing future research

Intention to publish date
01/06/2026

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