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The feasibility of telehealth in delivering parent-mediated early intervention targeting social communication in autism in Saudi Arabia

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Registration date 08/07/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/07/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a condition that affects how a person's brain develops. It can make it hard for them to interact and communicate with others. People with ASD often show repetitive behaviors and have very specific interests. Early treatment is crucial to help them develop better thinking and life skills and to lessen the impact of ASD.

Unfortunately, in rural areas of the United States, Australia, and Saudi Arabia, there aren't enough services to help people with ASD. Researchers suggest that one way to fix this problem is to get parents more involved in the therapy process and use technology like telehealth, which allows for remote therapy sessions.

Telehealth has been shown to lower costs and make it easier for doctors and therapists to help more patients than traditional in-person visits. In Saudi Arabia, many families have to travel far from home to get these services. This study looks at whether it's possible to teach parents to carry out therapy at home using telehealth. The goal is to see if this method works well, is easy to use, and is accepted by families in Saudi Arabia.

Who can participate?
Arabic speaking caregiver having a child aged less than 6 years old diagnosed with ASD.

What does the study involve?
The child will be assessed before intervention using the social-communication questionnaire, which is used to assess child's risk for autism. Vineland-II, which is used to assess child's adaptive behaviours, and ADOS-2 if not assessed before. ADOS-2 take 45-60 minutes approximately and will be administered to confirm ASD diagnosis and severity. The tests will be administered to ensure your child is suitable to take part in the study.

Taking part in the study involves a 30-min introductory session (in-clinic or from home) to talk about the intervention nature and goals. Before starting the intervention sessions, child's social-communication skills will be evaluated. The parent will be given a box with a small selection of

toys, and will be asked to play with the child as they do at home. The researcher will collect 10-minutes video of parent-child unstructured interaction, so we can assess child's social-communication skills before we start the training. Then, the parent will be offered a series of eight coaching sessions; once a week over eight weeks. Each session will last for one hour. The session will take place over the internet using video-conferencing with the therapist. A trained speech and language pathologist will provide all the intervention sessions.

In each session, the parent will be taught strategies to enhance child's social-communication skills. For example, the parent will learn how to achieve balanced turns in interactions, how to adjust the environment to support child's attention and engagement, and how to create lots of practice opportunities. Following each session, the parent will be asked to spend around 30 minutes daily in practising the strategies at home during everyday activities. Each week the parent will be asked to video 5-minutes of their interaction with the child the day before your session with the therapist. In the session, the parent will talk through the video with the therapist as part of the training.

At the end of the last session, the parent will be given an appointment to re-evaluate child's social-communication skills. The researcher will collect 10-minutes video of the parent playing with their child in the clinic to allow us to compare the progress after the intervention. Then, the parent will be asked to complete a short questionnaire about their experience of using video-conferencing for therapy.

What are the possible benefits and risks of participating?
Participating in this study will restrict the child from receiving regular speech therapy sessions while the study being conducted. However, child can resume the speech therapy sessions right after finishing the intervention. In the unlikely event that the therapist becomes concerned about you or your child, the therapist will seek assistance from a senior psychologist to help in the matter.

It is possible that the participated parent/caregiver feel uncomfortable to share video-recorded parent-child interaction due to concerned about how videos will be stored and who will have access to them. However, parent/caregiver will be informed that the videos will be used for feedback and training purposes only and that all materials will be stored securely and will be destroyed right after being coded. Parent/caregiver will also be informed that they have the choice to participate or not and will be informed about their right to withdraw at any time.

Where is the study run from?
University of Reading (UK)

When is the study starting and how long is it expected to run for?
January 2019 to January 2021

Who is funding the study?
Medical Services Department at Ministry of Defence (Saudi Arabia)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1223

Study information

Scientific Title
Telehealth-delivered parent-mediated early intervention targeting social communication in autism in Saudi Arabia: A feasibility study

Study objectives

The study investigated the intention of use, implementation, usability, and acceptability of telehealth in coaching caregivers of autistic preschoolers in the Saudi context. Previous research on this topic was done in Western contexts.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 14/07/2019, Scientific Research Centre Ethics Committee at Prince Sultan Military Medical City (As Sulimaniyah 7135, Riyadh, 12233, Saudi Arabia; +966 114777714; rec-psmmc@psmmc.med.sa), ref: 1142 and 1223

2. approved 02/12/2019, King Abdullah bin Abdulaziz Hospital Academic and Training Affairs (Airport Road, Riyadh, 11564, Saudi Arabia; +966 118200000; ata-research@kaauh.edu.sa), ref: RO2019-O-006

3. approved 10/09/2019, University of Reading Research Ethics Committee (Whiteknights House, Reading, RG6 6UR, United Kingdom; +44 1183784697; urec@reading.ac.uk), ref: 18/57 and 19/31

Study design
Interventional non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coaching parents of autistic children aged 6 years old or below using video-conferencing.

Interventions
1. Initial diagnostic session: children will be assessed before the intervention using the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) if not assessed before. ADOS-2 take 45-60 minutes approximately and will be administered to confirm ASD diagnosis and severity to describe the sample.
2. Pre-intervention session: during this session, an introductory meeting and the baseline of parent-child interaction measure (PCIM) a will be done which was developed for this study. Each parent and child pair will be video recorded for 10 minutes during unstructured play. The introductory meeting is expected to take 60-min to talk about the intervention goals and how the video-feedback will be implemented. During the introductory session, the caregiver will be encouraged to ask question to ensure that the procedures are clear. In this session, the telehealth platform will be introduced.
3. The intervention (8 sessions): caregivers will be coached in 8 consecutive sessions in 8 weeks (one 60-min session/week). In each session, the caregiver will be given goals and strategies to enhance child's social-communication skills; for example, how to follow their child's lead during play and how to achieve balanced turns in interaction with their child. Following each session, the caregiver will be asked to spend around 30 minutes daily in practising the strategies at home. She will be asked to record a 5-min video of her interaction with the child the day before meeting the therapist. Therefore, a total of 8 videos, a video following each coaching session will be requested from the caregiver.

4. Post-intervention session: the parent-child interaction measure (PCIM) will be administered after the intervention. Also, participants will be asked to complete an Arabic version of the Telehealth Usability Questionnaire (TUQ). TUQ is a 21-item tool expected to be completed in 5 minutes which was developed to evaluate the usefulness, ease of use, reliability, and satisfaction (Parmanto et al., 2016).

Intervention Type
Behavioural

Primary outcome(s)
1. Patient record was reviewed to collect the scores of the following tests if available; Autism Diagnostic Observation Schedule- Second Edition (ADOS-2; Lord et al. 2012), Social Communication Questionnaire Lifetime (SCQ; Rutter et al., 2003), and Vineland Adaptive Behaviour Scale, Second Edition (VABS-II; Sparrow et al., 2016). These measures used to describe the sample, not outcome measures.
2. Intention to use questionnaire (ITUQ) developed from the Technology Acceptance Model (TAM-21) (Hu et al., 1999) and the Telehealth Acceptance Measure (MALT-TAM) (Gorst et al., 2014) for the study was gathered from the population prior to recruiting for the feasibility trial.
3. The Telehealth Usability Questionnaire (TUQ) is a 21-item tool that was developed to evaluate the usability of using multi-purpose platforms (Parmanto et al., 2016) was collected post-intervention.
4. Intervention fidelity was measured for each participant from the observation of 5-min video-recorded parent-child interaction shared weekly. This method was adapted from Heitzman-Powell et al. (2014). Parent's application of each strategy was given a score from zero to two (2= fully achieved, 1= partially achieved, or the parent missed some opportunities, and 0= fails to achieve).

Key secondary outcome(s))
1. Child's social communication skills and parental synchrony were measured using Parent-child Interaction Measure (PCIM); a direct behavioural observation measure was used to code a 10-min video of parent-child dyadic interaction pre- and post-intervention that was developed for this study.
2. Therapists' fidelity of implementation was assessed using a 9-item tool adapted from McDuffie et al. (2013). The tool uses a 5-point Likert scale to evaluate the therapist's behaviour. Implementation fidelity assessment was carried out live by two raters from one randomly selected coaching session for each therapist.

Completion date
30/01/2021

Eligibility

Key inclusion criteria
1. Are Arabic speaking caregiver having a
2. Child age ≤6 years old and parent age is not restricted
3. Diagnosed with ASD using the Autism Diagnostic Observation Schedule, 2nd Edition (ADOS-2) and clinical judgments by a multidisciplinary team
4. With or without co-occurred developmental conditions (such as, Attention Deficit Hyperactivity Disorder)
5. Have no uncorrected auditory, visual or motor impairment severe enough to interfere with the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
6 years

Sex
All

Total final enrolment
11

Key exclusion criteria
Scoring < 40 in the Leiter-3 IQ scores, which suggests severe cognitive delay

Date of first enrolment
11/09/2019

Date of final enrolment
30/01/2021

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Prince Sultan Military Medical City
Riyadh
Saudi Arabia
12233

Study participating centre
King Abdullah bin Abdulaziz University Hospital
Riyadh
Saudi Arabia
11564

Sponsor information

Organisation
University of Reading

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
Medical Services Department at Ministry of Defence, Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Wafa Alatar walatar@psmmc.med.sa

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			05/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			18/07/2024	No	No