Clinical Study Protocol

1. Study title:

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

- 2. Trial registration: ISRCTN registry.
- **3. Funding:** This study was supported as part of a PhD scholarship funded by Medical Services Department, Ministry of Defence, Riyadh, Kingdom of Saudi Arabia.

4. Role and responsibilities:

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5. Introduction and rationale for the study:

The prevalence of children identified with autism spectrum disorder (ASD) is 1% to 1.8% globally (Elsabbagh et al., 2012). Parents have reported insufficient autism services across different countries in the world (Alnemary, et al., 2017; Corcoran et al., 2015; Daniels et al., 2017). The increasing prevalence of ASD has provoked widespread public health concern about the generated gap between available resources and consumer demand (Green, 2019). Early intervention (EI) is recommended practice for autistic children within national guidelines for autism in many countries in the world. Evidence for the importance of EI is supported by critical periods of brain development and connectivity. EI is particularly critical for autistic children because, without intervention, the deficits associated with ASD can negatively affect their learning and developmental progress.

Early intervention can be delivered to the autistic child by a therapist, i.e., therapistdelivered intervention, and can be delivered by a parent or caregiver, i.e., parent-mediated intervention (Oono et al., 2013). To be able to provide an effective EI program, researchers suggested actively engaging parents in therapy implementation (Bottema-Beutel et al., 2014). In parent-mediated interventions, the parent is the agent of change, and the child is the direct beneficiary of intervention. Parent training programs and parent coaching methods have been found to lead to better generalisation and maintenance of skills than therapist-implemented interventions (Kashinath et al., 2006; Pickles et al., 2016). To solve the inequity of accessing intervention services, researchers suggest redesigning service delivery systems by actively engaging parents in therapy implementation (Green, 2019; Oono et al., 2013). In addition, the use of telehealth will help overcome the barriers that time and distance create for underserved groups (Burke & Hall, 2015; Knutsen et al., 2016).

A survey completed by 205 families of autistic children in the Kingdom of Saudi Arabia (KSA) showed that 29% of the families travel outside their cities of residence to another city or country to receive EI services, especially those who live in non-major cities (Alnemary et al., 2017). The existing evidence on the effectiveness and feasibility of using telehealth in coaching parents of autistic children using naturalistic developmental behavioural interventions is limited. Also, current evidence on coaching parents remotely have been conducted in Western countries (Alatar et al., 2024). In the Saudi context, little is known about the feasibility of delivering parent-mediated early intervention targeting social communication skills.

The KSA is divided geographically into 13 provinces. 98% of the Saudi population aged 10-74 years have access to the internet in all provinces (CST, 2021). The expansion of telehealth services was initiated by the Ministry of Health (MOH) in a qualitative shift with the Saudi Vision 2030. The aim to evaluate the feasibility of telehealth as a way to deliver early interventions for autistic children is well aligned with the Saudi Vision. The Health Sector Transformation Program aims to improve quality and efficiency and promote equity in healthcare services in the KSA (Saudi Vision 2030, n.d.). One of the key objectives of the Health Sector Transformation Program introduced by the Saudi government is to improve access to health services through comprehensive coverage and equitable geographical distribution. The Health Sector Transformation Program is committed to cover 88% of the Saudi population, including those in rural areas with health services by 2025.

Introducing telehealth as a novel service delivery approach requires further research to investigate potential issues that could arise during remote coaching (Lerman et al., 2020). To our knowledge, the literature on telehealth application in the KSA generally and feasibility of telehealth is explicitly limited. Indeed, the research using reliable and validated Arabic measures of telehealth usability is immature. There is a need to develop or adopt telehealth measures to be used in effectiveness trials and patient experience studies conducted in Arab populations. The purpose of this study is to focus on how the parent-mediated early intervention program can be successfully implemented using the telepractice in the Saudi context. The study will investigate critical areas of feasibility as intention to use, implementation, usability, acceptability, and adherence to intervention. In addition, the study will evaluate the efficiency of the resources developed or adapted for this context, e.g., outcome measures.

6. Study objectives:

- To investigate caregivers' intention to use and adhere to the intervention, including recruitment and retention.
- To investigate the acceptability, implementation, and practicality of telehealth to deliver parent-mediated intervention for young autistic children in the Saudi context.
- To evaluate the usability of outcome measures.

7. Study design:

- Prospective, interventional, non-randomised design, without a control group, feasibility study.
- Conducted from January 2019 to January 2021 at two community-based settings.

8. Ethical compliance:

- Conducted in accordance with University of Reading code of good practice in research.
- Ethical approvals obtained from University of Reading Research Ethics Committee, Scientific Research Centre Ethics Committee at Prince Sultan Military Medical City (PSMMC), and King Abdullah bin Abdulaziz Hospital Academic and Training Affairs.
- Informed consents obtained from all participants.

9. Study population:

• Inclusion criteria:

- 1. Arabic speaking caregivers: caregiver/parent age is not restricted.
- 2. Child age ≤ 6 years old.
- 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.

• Exclusion criteria:

1. Scoring < 40 in the Leiter-3 IQ scores, which suggests severe cognitive delay.

10. Sample size:

- Target number: 24 participant. Sample between 24 and 50 have been recommended to estimate the standard deviation which will be used in a sample size calculation for a full-scale trial.
- Total final enrolment: 11 participant.

11. Intervention groups:

- One group received parent-mediated intervention delivered remotely.

12. Intervention details:

- Parents completed eight 60-min intervention sessions delivered remotely via videoconferencing.
- Video-feedback method was done following each session using 5-min videorecording of parent-child interaction.
- The intervention is a naturalistic developmental behavioural early intervention program developed from a community-based setting, the PSMMC, for this study.
- The intervention targets developmental skill in each session i.e., joint attention, dyadic interaction, play skills, turn-taking, imitation, nonverbal communication (over in two sessions), and verbal communication.

13. Outcome measures:

Patient record was reviewed to collect the scores of the following tests if available; Autism Diagnostic Observation Schedule- Second Edition (ADOS-2), Social Communication Questionnaire Lifetime (SCQ), and Vineland Adaptive Behaviour Scale, Second Edition (VABS-II). These measures used to describe the sample, not outcome measures.

• Primary outcome measures:

- 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 (Appendix 1).
- 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) see Appendix 2.
- Intervention fidelity was measured using observation of 5-min video-recorded parent-child interaction. 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).

• Secondary outcome measures:

- 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 (Appendix 3).
- 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 that was developed for this study (Appendix 4).

14. Data collection and analysis:

- ITUQ was gathered from the population prior to recruiting for the feasibility trial.
- TUQ was collected post-intervention.
- Intervention fidelity was measured for each participant from the observation of 5-min video-recorded parent-child interaction shared following each intervention session.
- Implementation fidelity assessment was carried out live by two raters from one randomly selected coaching session for each therapist.
- PCIM was collected pre- and post-intervention.
- The videos were coded using Behavioural Observation Research Interactive Software (BORIS) (Friard & Gamba, 2016).
- Analyses were run using IBM SPSS Statistics (Version 27).

15. Safety monitoring:

- In the unlikely event that the therapist becomes concerned about the child, the therapist will seek assistance from a senior psychologist to help in the matter.

16. Documentation and reporting:

- Detailed documentation of intervention sessions e.g., goals, technical issues, and troubleshooting.
- Comprehensive reporting of results including non-adherence to protocol.

17. Consent forms:

- Written informed consents obtained from all participants (caregivers of patients). All participants consented to participate in the study and use of data.

18. Ethical considerations:

- All materials stored securely and will be destroyed right after being coded.
- Videoconferencing platform is HIPAA compliant, has AES 128-bit encryption with an end-to-end encryption option and a locked meeting feature.
- Respect patient confidentiality.

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Appendix 1 Intention to Use Questionnaire (ITUQ)

استبانة مدى التقبّل

مكان السكن:

تمت التعبئة من قبل الأم الأب آخر

القسم الأول- التجارب السابقة.	نعم		لا		
سمعت عن الطب الاتصالي من قبل.					
استخدمت خدمات الطب الاتصالي من قبل.					
لو قمت بإجابة السؤال الثاني ب"نعم"، يرجى ذكر أي نوع من					
وسائل الطب الاتصالي قمت باستخدامه؟					
القسم الثاني- نية الاستخدام.	أو افق بشدة	أوافق	لا أوافق ولا أرفض	لا أوافق	لا أوافق بشدة
استخدام الطب الاتصالي لخدمة المريض فكرة جيدة.					
أعتقد أن الطب الاتصالي قد يكون مفيداً في خدمة طفلي.					
أنوي استخدام الطب الاتصالي لخدمة طفلي اذا أصبح متوفر آ.					
أعتقد أن لدي القدرة على استخدام الطب الأتصالي لمساعدة طفلي.					
الأشخاص المهمين بالنسبة لي سوف يسمحون باستخدامي للطب					
الاتصالي.					
عند ضمان الخصوصية، لا مانع لدي من استخدام فيديو خاص بي					
وبطفلي مع الأخصائية كجزء من الطب الاتصالي.					
القسم الثالث- في تجربة استخدام الطب الاتصالي مع حالات					
اضطراب طيف التوحد سوف يتم استخدام مقاطع فيديو توضح					
التفاعل بين الوالدين والطفل المصاب لإعطائهم التوجيهات كجزء					
من التدريب.					
ساكون مهتما بالمشاركة في البحث المتضمن على تجربة الطب					
الاتصالي في التدخل المبكر لأضطر أب طيف التوحد.					
لا مانع لدي من مشاركة مقطع فيديو مع الاخصانية الباحتة في جلسة · الألب الدين					
الطب الانصالي. مرابع					
لا مانع لذي من مشاركة مقطع فيديو مع الاخصائية الباحنة ومع باحنة . «ارتباط الله الله الله الله الله ال					
للاية في جلسة الطب الانصالي. أُن الأبر لهُ تالدانت بنا الذير الخرارية، ممان					
ساسمح للأحصانية الباحثة بحفظ الفيديو لمساهدته من 6 أحرى في فتسلام من المنابقين من ذقب النور مدير ذلك					
وقت لا حق، مارحظة إسليم حدف القديو بعد ذلك إ أ الماه المشالمة المنتر منالك ما ها بدين مأن					
ساسمح للاحصائية الباحثة بحفظ الفيذيق لمشاهدته مرة آخرى في ************************************					
وقت لاحق مع باحده تأثيه. ملاحظة: سيبم حدف القديو بعد دلك.					

Appendix 2 Telehealth Usability Questionnaire (Arabic)



University of Pittsburgh

School of Health and Rehabilitation Sciences

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استبانة سهولة استخدام الطب الاتصالي

	7	6	5	4	3	2	1		غ/م		
موافق								لا أوافق		الطب الاتصالي يحسن من وصولي إلى خدمات الرعاية الصحية.	1
موافق								لا أوافق		الطب الاتصالي يوفر علي الوقت المبذول في السفر إلى المستشفى أو العيادة المتخصصة.	2
موافق								لا أوافق		الطب الاتصالي يزودني باحتياجي من الرعاية الصحية.	3
موافق								لا أوافق		كان استخدام هذا النظام بسيطاً.	4
موافق								لا أوافق		كان من السهل تعلم استخدام النظام.	5
موافق								لا أوافق		أعتقد انه يمكنني أن أصبح منتجاً بسر عة باستخدام هذا النظام.	6
موافق								لا أوافق		الطريقة التي أتفاعل بها مع هذا النظام مرضية.	7
موافق								لا أوافق		أحب استخدام النظام .	8
موافق								لا أوافق		النظام بسيط وسهل الفهم .	9
موافق								لا أوافق		هذا النظام قادر على القيام بكل ما أريد منه القيام به.	10
موافق								لا أوافق		يمكنني التحدث بسهولة إلى الممارس الصحي بواسطة نظام الطب الاتصالي.	11
موافق								لا أوافق		يمكنني سماع الممارس الصحي بوضوح بواسطة نظام الطب الاتصالي.	12
موافق								لا أوافق		شعرت بأنني قادر على التعبير عن ذاتي بشكل فعال.	13
موافق								لا أوافق		باستخدام نظام الطب الاتصالي، أستطيع رؤية الممارس الصحي كما لو أنني قابلته شخصياً.	14
موافق								لا أوافق		أعتقد أن الزيارات المقدمة عبر نظام الطب الاتصالي تعادل الزيارات الشخصية.	15
موافق								لا أو افق		كلما أخطأت في استخدام النظام، أستطيع تعديل الخطأ بسهولة وبسرعة.	16

أعطى النظام رسائل عطل أرشدتني بوضوح إلى كيفية إصلاح المشاكل.	لا أوافق				موافق
أشعر بالراحة أثناء التواصل مع الممارس الصحي باستخدام نظام الطب الاتصالي.	لا أو افق				موافق
الطب الاتصالي طريقة مقبولة لتلقي خدمات الرعاية الصحية.	لا أوافق				موافق
أود استخدام خدمات الطب الاتصالي مجدداً.	لا أو افق				موافق
بشكل عام، أنا راض عن نظام الطب الاتصالي.	لا أو افق				موافق

يرجى تزويدنا بتعليقاتك حول نظام الطب الاتصالي:

Appendix 3 Implementation Fidelity

Ite	m	5	4	3	2	1
1.	Engages in conversations and information sharing with					
	parent.					
2.	Provide descriptive praise for successful strategy use.					
3.	Encourages parent to implement all the strategies targeted in the selected session					
4.	Encourages parent to comment on successful/ unsuccessful strategy use.					
5.	Model strategy use with accompanying explanation.					
6.	Encourages parent to reflect on strategy use and elicit individualized examples of activities.					
7.	Models language/vocalizations describing child's focus of attention.					
8.	Models verbal or non-verbal behaviour in response to child's communication acts.					
9.	Actively listens and problem solves with parent.					

Scores definitions:

- 5 The clinician engaged in described behaviour **throughout** the session.
- 4 The clinician engaged in described behaviour **most** of the time.
- 3 The clinician engaged in described behaviour some of the time.
- 2 The clinician engaged in described behaviour **rarely** throughout the session.
- 1 The clinician **failed** to engaged in described behaviour throughout the session.

Appendix 4 Parent-Child Interaction Measure (PCIM)

Domain	Code	Subject	Definition
Social communication	Initiated joint attention	Child	Spontaneous initiation of joint attention by shifting her/his eye gaze from an object to the parent, for the purpose of sharing a topic or focus with the parent, either action, feelings/emotions, experiences, games, or objects. It involves a reference to the parent and the object by coordinated looking, showing, or giving.
			 Do NOT use this code if the child's initiation may have been elicited by parent's movement or verbalisation. The child does NOT have to look back at the object. Use this code if the child IJA using eye gaze accompanied with pointing for the purpose of showing. Use this code if the child IJA using eye gaze accompanied with verbal behaviour, i.e., comment, naming object, etc.
	Responding to joint attention	Child	Response to joint attention elicited by the parent. The child must shift her/his eye gaze following parent's eye gaze or pointing gesture to an object for the purpose of responding to a topic or focus with the parent, e.g., parent says 'Look! and point toward something or by pointing/gesture only. It involves a reference to the object by coordinated looking, acknowledgement of parent's focus, showing, sharing, or giving.
	Imitation	Child	 The child must clearly follow the shift in parent's eye gaze, pointing, or gesture by immediately turning his/her head and eyes to the appropriate area where the object is located. This code is used for child's intent to imitate the parent using physical, gestural, vocal and speech behaviours with appropriate intonation.
	Social communication	Child	 This code of imitation must always be spontaneous (not physically prompted). This code is used for the imitation of conventional and unconventional gestures. Conventional gestures are gestures with social meaning, e.g., nodding instead of "yes" or shaking head for "no". Unconventional gestures are gestures with no social meaning, e.g., drinking out of a toy cup. Child's attempt to repeat parent's speech or vocalisations with identical intonation is considered echolalia and must NOT be scored using this code. This code is used for any meaningful context-related communication act produced by the child for the purpose of socialising without coordinated looking.
	act		 Use this code for any communication act verbal or non-verbal, in which the child is communicating for the purpose of sharing, giving or showing, e.g., pointing for the purpose of sharing an event or pointing for the purpose of showing the parent an object without coordinated looking. Use this code for any verbal communicative act, e.g., comments produced by the child for the purpose of spontaneously referring to an event, object, person, or action, without coordinated looking. Do NOT use this code if the child produced verbal behaviour, e.g., comment or statement in response to parent's question or statement (elicited by parent).

			- Self-directed verbal communicative act must NOT be coded unless they are clearly part of social interaction with the parent.
	Terminating	Child/	This code is used when social interaction is terminated by the child or the parent. The child may end a social interaction
	social interaction	Parent	by running away from the parent, shifting his attention to a new object or action, or by using avoidance behaviours, e.g., crying or lying on the floor. The parent may end a social interaction by talking to the therapist or answering a phone call.
Requesting Initiated request	Initiated request	Child	This code is used for any communicative act initiated by the child, verbal, non-verbal, or both, where an object or action (e.g., to open a snack or to blow bubbles) is requested with or without coordinated looking. This code is also used when the child requests a game or activity, i.e., tickling.
	Prompted request	Child	This code is used for any child's communicative act, verbal, non-verbal, or both, prompted by the parent, where an object or action (e.g., to open a snack or to blow bubbles) is requested with or without coordinated looking.
Synchrony	Asynchronous	Parent	 Use this code when the parent prompts the child either verbally and/or non-verbally, including full or partial physical prompting and gestural prompting. This code is used for any synchronised face-to-face interaction aimed to support and facilitate the behaviour of the child
communication		for the purpose of initiating and maintaining the flow of the interaction and child's attention by acknowledging child's focus of interest and using timely reciprocal communication.	
			- This code is used for any verbal communicative act produced by the parent, including comments, statements, and acknowledgement.
			- This code is also used for any non-verbal communicative act produced by the parent, including movements and facial expressions.
			 Use this code when parent imitates the child's either verbally or through movements and gestures. This code is used ONLY when child is attending, or parent must wait until the child is refocused, pacing their actions to maximise the child's attention, i.e., pausing to give the child a chance to act.
Synchronous communicatior	Synchronous communication	Parent	This code is used for any synchronised face-to-face interaction aimed to support and facilitate the behaviour of the child for the purpose of initiating and maintaining the flow of the interaction and child's attention by acknowledging child's focus of interest and using timely reciprocal communication.
			- This code is used for any verbal communicative act produced by the parent, including comments, statements, and acknowledgement.
			- This code is also used for any non-verbal communicative act produced by the parent, including movements and facial expressions.
			 Use this code when parent imitate the child's either verbally or through movements and gestures. This code is used ONLY when child is attending, or parent must wait until the child is refocused, pacing their
			actions to maximise the child's attention, i.e., pausing to give the child a chance to act.