ISRCTN14156001 https://doi.org/10.1186/ISRCTN14156001

Feasibility study of an randomised controlled trial to investigate the whether a robot (KASPAR) can improve the social skills of children with an Autism Spectrum Disorder

Submission date
20/02/2017

Recruitment status
No longer recruiting

Registration date
23/02/2017

Overall study status
Completed

Last Edited
22/11/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Autism Spectrum Disorder (ASD) is a common disorder that affects the way that a person communicates and relates to others. It is a spectrum condition therefore the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. It is associated with difficulties in social communication/interaction and restricted, repetitive patterns of behaviour, interests or activities. ASD is a disabling condition, but early treatment increases the likelihood of improved long-term outcomes. However, parents frequently report waiting a long time for a diagnosis for their child and express feelings of dissatisfaction with the availability of interventions. One avenue of research has explored the use of Socially Assisted Robots (SARs) in supporting the social and emotional development of children with ASD. The SAR, KASPAR, has been used in studies aiming to improve the development of communication and social skills in children with ASD, particularly those of a young age, with promising results. Children play games with KASPAR, which aim to promote important skills for the development of social competence. Over a number of case studies, teachers, parents and carers have reported improvements in children's behaviour, suggesting some benefits of robot mediated interventions. The aim of this study is to conduct a small study to find out if a full-scale trial comparing the social skills of children who interact with KASPAR and children who interact with a researcher only would be possible.

Who can participate?
Children newly diagnosed with ASD.

What does the study involve?
Participants randomly allocated to one of the groups. Children are given two 15 minute familiarisation sessions with the therapist and/or the robot which take place in a room with a one way mirror, so that parents can watch what it happening. Then, there are six therapy sessions lasting up to 20 minutes. During these sessions, the child plays "games" that include aspects of joint attention, turn taking and imitation. All the games include these skills, so the

therapist can select the games according to the preference/ability of each child. Those children who are in the Therapist only group receive the program with KASPAR at the end of their involvement with the study. Parents are asked to complete questionnaires about their child's behaviour and their own stress levels at the start of the study, soon after the program has finished (at 10 weeks) and 3 months after the program has finished (at 22 weeks).

What are the possible benefits and risks of participating?
Children and their parents are expected to benefit from receiving an intervention which is expected to improve their social communication skills. There are no notable risks involved with taking part.

Where is the study run from?
Peace Children's Centre (UK)

When is the study starting and how long is it expected to run for?
December 2016 to November 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Karen Irvine
k.irvine2@herts.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Karen Irvine

ORCID ID
https://orcid.org/0000-0003-4087-3802

Contact details
University of Hertfordshire
Health Research Building
College Lane
Hatfield
United Kingdom
AL10 9AB

Additional identifiers

Protocol serial number
32090

Study information

Scientific Title
Feasibility study of an randomised controlled trial to investigate the effectiveness of a humanoid robot to support social skills development in children with an Autism Spectrum Disorder

Acronym
KASPAR RCT

Study objectives
The aim of this study is to assess the feasibility of conducting a full-scale randomised controlled trial comparing the social skills of children who interact with KASPAR, a Socially Assisted Robot (SAR), and children who interact with a researcher only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Cambridge REC, 18/11/2016, ref: 16/EE/0387

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: General Paediatrics; UKCRC code/ Disease: Mental Health/ Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Interventions
The child will be randomised, using a database, to either the KASPAR group or the Therapist only group (TOG). The child will then be randomised, using a database, to either the KASPAR group or the Therapist only group (TOG). The child will be allocated to a waiting list for a clinic, if there are no clinical appointments available.

There will be 20 children recruited into each group. The KASPAR group will consist of children who will have an intervention with KASPAR and the therapist. The Therapist Only Group (TOG) will consist of children who will play the same games, but with the therapist.

Sessions will run weekly. Children will be given two 15 minute familiarisation sessions with the therapist and/or the robot. These will take place in a room with a one way mirror, so that parents can watch what it happening. Then, there will be six therapy sessions lasting up to 20 minutes. During these sessions, the child will play “games” that include aspects of joint attention, turn taking and imitation. All the games include these skills, so the therapist can select the games according to the preference/ability of each child.

The follow up involves meeting with families and asking them to complete the same RCT outcome measures that were administered at baseline. Parents will be asked to complete questionnaires about their child's behaviour and their own stress levels (the outcome measures) at three time points; before the intervention (at time 0), soon after the intervention has finished (at 10 weeks) and 3 months after the intervention has finished (at 22 weeks).

Intervention Type
Other

Primary outcome(s)
Feasibility outcome measures:
1. Recruitment rate is assessed by recording the number of participants who consent to take part in the study (per month) during the 11 month recruitment period
2. Attrition rate is assessed by recording the percentage of participants in each arm of the study who fail to remain in the study until the last data collection point (i.e. 22 weeks after completing the intervention)
3. Outcome measure completion rate is assessed by recording the percentage of each of the questionnaires (RCT outcome measures) that are fully completed by study participants
4. Suitability of outcome measures for the main study is assessed through qualitative interviews with 50% of the study participants after the last data collection point (i.e. 22 weeks after completing the intervention)
5. Feasibility of collecting data for an economic analysis in a definitive trial is assessed using qualitative interviews with participants after the last data collection point (i.e. 22 weeks after completing the intervention). And by the percentage of questionnaires that are fully completed by study participants.
6. Acceptability of the intervention to parents and clinicians is assessed by qualitative interview with parents, children (where appropriate) and clinicians at the end of the study
7. Practicality of running the clinics where the intervention is delivered in the NHS setting is assessed during a qualitative interview with clinicians at the end of the study

Key secondary outcome(s))
1. Changes in behaviours associated with ASD are measured using the Social Communication Questionnaire (SCQ) and the Social Skills Improvement System (SSIS) at baseline 10 and 22 weeks
2. Parental stress is measured using the Parenting Stress Index 4 (PSI-4) at baseline 10 and 22 weeks
3. Quality of life of the child is measured with the Child Health Utility 9D (CHU-9D) at baseline 10 and 22 weeks
4. Health Economic benefits ree assessed using the Child and Adolescent Service Use Schedule (amended version) at baseline 10 and 22 weeks

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Male and female children aged 5-10 years
2. Diagnosis of an ASD confirmed by a clinician using ADOS and/or ADI
3. Able to understand or fluently speak English
4. IQ is above 70

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
10 years

Sex
All

Key exclusion criteria
1. Currently in receipt of a privately-delivered social communication intervention (i.e. not part of NHS or education usual care)
2. The child is non-English speaking or if non-verbal, unable to understand English
3. Carer who is completing the questionnaire is unable to do so in English

Date of first enrolment
01/03/2017

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Peace Children's Centre
Peace Prospect
Watford
United Kingdom
WD17 3EW

Sponsor information

Organisation
Hertfordshire Community NHS Trust

Organisation
University of Hertfordshire

Organisation
Hertfordshire Community NHS Trust

ROR
https://ror.org/013sryf19

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/06/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes