ISRCTN83964946 https://doi.org/10.1186/ISRCTN83964946

Systemic Autism-related Family Enabling (SAFE) study

Submission date
20/11/2017

Recruitment status
No longer recruiting

Registration date
20/11/2017

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Autism is a lifelong disorder that affects how people communicate and relate to others and to the world. Autism affects more than 1% of the UK population. Children with autism (CWA) have communication problems and often have challenging behaviour. The families of CWA often have problems with their mental health and may need help to manage the difficulties associated with autism. Family wellbeing and life chances are often poor. The care received by families following diagnosis is currently fairly limited. Systemic Autism Family Enabling (SAFE) is a specific therapy for families of CWA. SAFE is a therapy for the whole family and involves five three-hour sessions, three in the family home and two with other families, and a follow-up session for the intervention families. SAFE uses specially trained family therapists incorporating the most effective elements from various approaches, and uses visual materials and play-based approaches to explore aspects of autism, problem-solving, emotional wellbeing and coping strategies. SAFE was developed by a professional team with input from autism parent-experts from more than 90 families. Families are involved in the development of SAFE activities to ensure that the needs and outcomes they identified are met. Families are involved in the conduct of this study throughout. The results will be shared with policymakers, clinicians and families and in the future it is hoped that a larger study will show that SAFE is effective and can be used across the UK. The aim of this study is to assess the effectiveness of the SAFE therapy, and by running this feasibility study a larger study can be planned and delivered with confidence.

Who can participate?
Families that include a child who have been diagnosed with Autism aged three to 16 years old.

What does the study involve?
Participating families are randomly allocated to one of two groups. Those in the first group receive their usual support. Those in the second group receive the SAFE therapy. SAFE is a therapy for the whole family and involves five three-hour sessions, three in the family home and two with other families, plus a follow-up session. SAFE is delivered by specially trained family therapists and incorporates the most effective elements from various approaches. It uses visual materials and play-based approaches to explore aspects of autism, problem-solving, emotional wellbeing and coping strategies. Families are asked to complete various questionnaires and some are invited to talk to in depth about their experiences of participating in the study.

What are the possible benefits and risks of participating?
The SAFE family therapy sessions will involve discussing difficulties and may evoke emotions and stressful feelings. The therapists undertaking SAFE will be available to discuss any thoughts and feelings that participants have in between sessions and at the start of each session. There is a slight chance that the SAFE family therapy sessions could lead to an initial increase in family disagreements as family members learn how to change the way they solve problems and talk with one another. The SAFE study team includes trained therapists who are supervised by an experienced clinical psychologist, so appropriate support will be available to help with any difficulties that may arise.

Where is the study run from?
1. Plymouth University (UK)
2. Child Development Centre Scott Business Park (UK)
3. Childrens Care Management Centre (UK)
4. Royal Cornwall Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2017 to May 2019

Who is funding the study?
1. Autistica
2. National Institute for Health Research

Who is the main contact?
Sarah Campbell

Contact information

Type(s)
Public

Contact name
Ms Sarah Campbell

Contact details
Senior Trials Manager
Peninsula Clinical Trials Unit
Plymouth University
N16
ITTC Building 1
Plymouth Science Park
Plymouth
United Kingdom
PL6 8BX

Additional identifiers

Integrated Research Application System (IRAS)
213527

Protocol serial number
34613, IRAS 213527

Study information

Scientific Title
A multi-centred, randomised, controlled feasibility study comparing the SAFE intervention with support as usual for families of children with autism spectrum disorder. Systemic Autism-related Family Enabling (SAFE) study

Acronym
SAFE

Study objectives
The overarching aim of this study is to establish the feasibility of a definitive randomised controlled trial of Systemic Autism-related Family Enabling (SAFE) therapy for families of children with autism (CWA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 16/10/2017, ref: 17/SW/0192

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental health, Primary sub-specialty: Developmental disorders - Autism; UKCRC code/ Disease: Mental Health/ Disorders of psychological development

Interventions
The SAFE intervention is an intensive programme of systemic family therapy designed to treat Autism Spectrum Disorder (ASD) and mental health related difficulties encountered by families of children with autism (CWA). Each therapy session includes two therapists. Between weeks one and 16, families allocated to the SAFE intervention attend five three hour SAFE therapy sessions. Sessions 1 and 5 are multi-family sessions and take place in a community setting with appropriate insurance for the activities undertaken. Children, including the CWA do not need to be present at these sessions. Where group sessions are not possible, for example if one family is not available on a given date, group sessions may be replaced with home visits. Sessions 2, 3 and 4 takes place in the family home. The minimum number of family members that need to be present for a home session to take place is one parent and the child with autism. Where home visits are not possible, for example where there is a resident sick relative, home visits may be

replaced with sessions in a community setting. The therapists facilitate sessions which will be video recorded, as is usual practice for therapy sessions. The videotapes (and transcribed excerpts of the footage) are not part of the reported study data, they are only be used by the therapists in supervision sessions, in preparation for subsequent sessions, therapy process research and for training. The videotapes are kept in a locked cupboard at Plymouth University by the therapist supervisor.

Appointments are arranged at times to suit the participant families, and visit reminders are sent out to participants as appropriate. Where families do not attend or cancel sessions, these will be rescheduled. To encourage compliance with the programme, families are given 16 weeks to complete all therapy sessions. All sessions, whether completed or missed, are tracked and recorded within the study database. Following completion of the therapy programme, families attend a group follow-up session at 24 weeks post-allocation. Trained support workers from local voluntary groups attend this follow-up session and are invited to give the families information about continued support for families of CWA through existing networks.

Each session includes the following assessments are given to families to complete:
1. Client Satisfaction Questionnaire (CSQ-8)
2. The Helpful Aspects of Therapy Questionnaire (HAT)

A Between Session Activity (BSA) homework activity is given to families after each session. Families are given a pro-forma with key elements of the intervention as prompts. Families track strengths and difficulties in response to SAFE ideas. Families bring the completed activity to the following session. Therapists respond to the activity in the session and reflect on it in relation to the intervention process during supervision. Families are expected to spend at least 30 minutes every fortnight completing this activity.

In addition, there will be email or telephone conversation between therapists and family ("check-in time") in order to provide reassurance, collect feedback and plan home visits. At the end of each session the therapist will complete a training checklist and questionnaire (TCQ).

Participants in both study arms are followed up at 32 weeks

Intervention Type
Other

Primary outcome(s)
Global family function is measured using the SCORE 15 questionnaire at baseline and 32 week follow up.

Key secondary outcome(s))
1. Child behaviour is measured using the Child Behaviour Checklist (CBCL) questionnaire at baseline and 32 week follow up
2. Child-parent attachment is measured using the Coding of Attachment-Related Parenting for use with children with Autism (CARP-A) assessment at baseline and 32 week follow up
3. Anxiety & depression is measured using the Patient Health Questionnaire (PHQ-SADS) at baseline and 32 week follow up
4. Reflective Functioning is measured using the reflective functioning questionnaire (RFQ) at baseline and 32 week follow up
5. Caregiving Helplessness is measured using the Caregiving Helplessness Questionnaire (CGHQ) at baseline and32 week follow up

6. Economic outcomes (EQ-5D-5L, CHU-9D, and resource use questionnaires) are measured at baseline and 32 week follow up

Completion date
30/05/2019

Eligibility

Key inclusion criteria
1. Family includes child with ASD, aged 3-16 years
2. Diagnosis of ASD, severity level 1 or 2
3. Diagnosed within 12 months of consenting to the study
4. If other diagnoses are present, ASD must be primary diagnosis
5. Family are willing to comply with study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Children with ASD severity level 3
2. Children with ASD and intellectual impairment
3. Serious concomitant illness in child or family, or other circumstances such that they are unable to comply with study requirements
4. Families who may be a risk to safety of research staff
5. Insufficient English language, or capacity for parent/child to consent/assent to the study

Date of first enrolment
01/01/2018

Date of final enrolment
03/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plymouth University
Peninsula Schools of Medicine and Dentistry
ITTC Building 1
Plymouth Science Park
Plymouth
United Kingdom
PL6 8BX

Study participating centre
Child Development Centre Scott Business Park
Beacon Park Road
Plymouth
United Kingdom
PL2 2PQ

Study participating centre
Childrens Care Management Centre
The Autism Spectrum Disorder Assessment Team (ASDAT)
Truro Health Park
Infirmary Hill
Truro
United Kingdom
TR1 2JA

Study participating centre
Royal Cornwall Hospitals NHS Trust
Treliske
Cornwall
Truro
United Kingdom
TR1 3LJ

Sponsor information

Organisation
Plymouth Hospitals NHS Trust

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
Autistica

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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 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?
Results article	results	31/12/2020	11/01/2021	Yes	No
Protocol article	protocol	27/05/2019	11/05/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes