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A study of the use of safety plans to reduce self-harm and suicide for autistic adults

Submission date
03/07/2020

Recruitment status
No longer recruiting

Registration date
06/07/2020

Overall study status
Completed

Last Edited
24/06/2025

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
Suicide is much more common in adults who have a diagnosis of autism spectrum disorder than it is for people without this diagnosis, with some research indicating that autistic people are around nine times more likely to die by suicide than non-autistic people. The available evidence shows that 66% of autistic adults have considered suicide, this is much higher than the UK general population where the rate is about 17%. In addition, suicide is a leading cause of premature death for autistic people. Although autistic people are at increased risk of suicide, no research has yet explored the development of suicide prevention strategies. Research in to other types of mental health difficulties such as anxiety and depression indicates that autistic people require adaptations to be made to standard treatments to make them accessible and meaningful.

This research project aims to evaluate how acceptable and feasible an adapted version of a well-established suicide prevention strategy (Safety Plans) are for use with autistic adults with a history of self-harm, suicidal thoughts or suicidal behaviours.

Who can participate?
Autistic adults who have experienced self-harm or suicidal thoughts or behaviours in the last six months, family members of autistic adults who have experienced self-harm or suicidal thoughts or behaviours and professionals from social care and third sector organisations who provide support to autistic people.

What does the study involve?
This research project will be in three stages.

In stage 1 autistic adults, family members of autistic people and professionals working with autistic people will be consulted about the adapted safety plans and other aspects of the research plan to ensure that they are fit for purpose. Also, local authorities and mental health and autism charities and support groups will be collaborated with to train staff in how to introduce the adapted safety plans to autistic adults who have experienced suicidal thoughts and behaviours.

In stage 2 10 autistic adults will be recruited and asked to use the plans and complete a number of questionnaires about their thoughts, feeling and behaviours. Their feedback will be sought on all of these procedures, as well as feedback from their support workers.

In stage 3 a larger cohort of autistic adults who have experienced suicidal thoughts and feelings will be recruited from the same services. Participants will be allocated by a computer to either use the adapted safety plans or receive their usual care package. There will be follow-up appointments with these participants after one month and six months, where they will be asked to complete a range of measures about their thoughts feelings, and behaviours during this time. At the end of the study, the adults who received the adapted safety plans and their support workers will be asked whether they used the plan and what they thought about it.

What are the possible benefits and risks of participating?
Participation will involve thinking and talking about some difficult feelings and emotions. Sometimes people can find it difficult or upsetting to discuss sensitive topics such as self-harm, suicidal ideation and suicidal behaviours. In previous research, some participants have volunteered that having the opportunity to talk about these issues can be helpful.

Where is the study run from?
The study is being run by a team of experienced autism researchers at Newcastle University (UK) and Nottingham University (UK).

When is the study starting and how long is it expected to run for?
February 2019 to December 2023

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

Who is the main contact?
Dr Jacqui Rodgers
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
280742

Central Portfolio Management System (CPMS)
45326

Study information

Scientific Title
Adapted suicide safety plans to address self harm, suicidal ideation and suicide behaviours in autistic adults: an interventional single arm feasibility trial and external pilot randomised controlled trial

Acronym
AASP

Study objectives
The aims of this study are to evaluate the feasibility and acceptability of the use of autism adapted safety plans for autistic adults and to undertake an external pilot to explore whether the components of a larger future definitive trial are achievable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2020, MREC, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk), ref: 20/WA/0101

Primary study design
Interventional

Study design
Interventional single-arm feasibility trial and external pilot randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Intentional self-harm, autism spectrum disorder

Interventions
The intervention will be Autism Suicide Safety Plans (SPs), adapted in partnership with autistic people and those who support them, compared to usual care. SPs consist of a prioritized list of hierarchical steps that can be used prior to or during a crisis to mitigate the risk of self-harm and suicidal behaviour. The SP can be personalised to the individual’s needs and have proven efficacy in a range of clinical groups. The researchers' PPI with autistic people and those who support them has identified SPs as a promising intervention to prevent self-harm and suicide in autistic adults. So far, they have developed an adapted SP for autistic adults from the PPI event. The

intervention will be delivered in non-NHS settings (community, autism charities, and mental health charities), in addition to the care they usually provide their clients. In the stage three external pilot RCT, the researchers will recruit autistic adults who are accessing support from mental/autism charity partner organisations who have experienced self-harm. These autistic adults will be allocated at random, by a computer, to use the SPs (alongside usual care), or receive only usual care (1:1). The researchers will follow up with these participants 1 month and 6 months later and ask them about self-harm, depression, anxiety, and suicidal thoughts /behaviours. The researchers will also ask the autistic adults who received the SPs and their support workers if they used the plans and what they thought about them.

This study is comprised of 3 stages. Stage one will use a series of focus groups to further refine the adapted SPs, and develop the methods, materials and procedures for the study. The focus groups will be run in each of the two separate study sites (Universities of Newcastle and Nottingham). This will allow the research team to identify common themes between the groups and ensure that the adapted SPs are appropriate across the two different sites and slightly different settings where the intervention will be delivered.

Stage two of the study is a single-arm interventional feasibility study with ten autistic people recruited through third sector partner organisations. At the beginning of stage two, support staff from partner organisations will attend training workshops on the use of adapted SPs, delivered by the research team. Working with partner organisations autistic adults who meet the inclusion criteria will be identified and invited to participate in this stage of the study. Interested individuals will complete an expression of interest form granting permission for the research associates at each site to make contact with them to provide more information about the study and, where appropriate, obtain informed consent and undertake baseline assessments. 10 participants will be included in this stage, 5 at each site. If more autistic people express interest at this stage, with their permission, their contact details will be retained for stage 3. A trained support worker from the partner organisation that the autistic person was recruited from will be allocated to each participant (wherever possible this will be someone already known to the autistic person). The participant and their support worker will then complete the SP together, the participant can then use the SP as required. With permission, the session during which the SP is completed will be recorded to enable the research team to determine fidelity. It is anticipated that completion of the safety plan will take approximately 1 h. The support workers will inform the research associates at each site of the date of completion of the safety plans for each participant. One month after completion of the SPs the research associates will contact the autistic adult and their support worker to complete follow-up assessments. The outcomes for Stage 2 focus on the feasibility and acceptability of autism adapted SPs delivered via local authorities and third sector autism or mental health organisations.

Stage three involves an external pilot randomised controlled trial of the adapted safety plans. At the beginning of stage three further SP training workshops for support staff from partner organisations who were not able to participate in training during Stage 2 will be offered. Working with partner organisations autistic adults who meet the inclusion criteria will be identified and invited to participate. Interested individuals will complete an expression of interest form granting permission for the research associates at each site to make contact with them to provide more information about the study and where appropriate take informed consent and undertake baseline assessments.
After completing baseline assessments participants will be randomised to receive adapted SP and usual care or usual care. For participants randomised to the Adapted SP and usual care arm a trained support worker from the partner organisation that the autistic person was recruited from will be allocated (wherever possible this will be someone already known to the autistic person). The participant and their support worker will then complete the SP together, the

participant can then use the SP as required. With permission, the session during which the SP is completed will be recorded to enable the research team to determine fidelity. The support workers will inform the research associates at each site of the date of completion of the safety plans for each participant. Participants will be followed up after 1 and 6 months.

Intervention Type
Behavioural

Primary outcome(s)
Self-harm without intent to die will be assessed using a semi-structured interview; the Self Injurious Thoughts and Behaviours Interview (SITBI), at baseline, 1 and 6 months

Key secondary outcome(s)
1. Psychiatric status of participants, including suicidality, will be assessed with a semi-structured interview; the Mini International NeuroPsychiatric Interview at baseline, 1 and 6 months
2. Assessment of the presence of adverse/difficult life experiences will be assessed by questionnaire completion using the Vulnerability Experience Quotient at baseline, 1 and 6 months
3. Demographic characteristics including socio-economic status, employment, housing, access to support, physical health, education, major life events will be captured using a questionnaire at baseline and 6 months
4. Health-related quality of life in relation to mobility, self-care, usual activities, pain/discomfort and anxiety/depression measured using the EQ-5D-5L at baseline and 6 months
5. Health state utilities for use as part of a cost-benefit or cost-utility analysis will be assessed using a Health Economics Preference Elicitation tool developed for the study at baseline and 6 months
6. Information relating to participants' use of NHS, local authority and third sector services over the previous 6 months, captured using a Treatment as Usual/Usual Care Questionnaire designed specifically for the study at baseline and 6 months
7. An economic benefit assessment of the safety plan intervention will be assessed using an economic benefit assessment questionnaire at 6 months
8. How usable autistic adults find the safety plans will be captured using the questionnaire System Usability Scale (SUS) at 6 months
9. Participant satisfaction with the safety plans will be recorded using the Client Satisfaction Questionnaire-8 (CSQ-8) at 6 months
10. Interviews with the autistic adults who have participated to gain feedback on their views of the research methods, outcome measures and the safety plans, at 6 months
11. Interviews with support staff who have participated in the study to gain feedback on the views of the research methods, outcome measures, and the safety plans, at 6 months
12. The following will also be recorded:
12.1. The percentage of autistic participants approached during the first 4 months who consent to be randomised to the study and complete baseline assessments
12.2. The percentage of autistic participants who progress from identification/eligibility to beginning of treatment over the first 4 months
12.3. The number of sessions attended by autistic participants at 6 months
12.4. The number of participants who complete the assessments at the primary endpoint at 6 months
12.5. The percentage of participants who rate the usability of the safety plans on the System Usability Scale as 68 or above, at 6 months
12.6. The percentage of participants who report satisfaction with the intervention (indicated as a score >20 on the Client Satisfaction Questionnaire-8) at 6 months

12.7. Fidelity of delivery to the safety plan manual will be undertaken by experts on the delivery of SPs viewing the session with autistic adults during which the SP are developed and rating the session using a bespoke fidelity checklist

Completion date
14/12/2023

Eligibility

Key inclusion criteria
1. Adults with a clinical diagnosis of ASD
2. Accessing services via charities or third sector autism or third sector mental health services
3. A self-reported history of self-harm, suicidal thoughts or behaviours within the last 6 months
4. Sufficient spoken English to take part in assessments
5. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Insufficient English language skills or literacy to complete the SP and outcome measures (in a future definitive trial we will aim to develop versions of the materials in a range of languages)
2. Current psychotic symptoms

Date of first enrolment
10/09/2020

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
Newcastle
United Kingdom
NE1 4LP

Study participating centre
Nottingham University
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129196

Funder Name
National Institute for Health Research (NIHR) (UK)

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 datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jacqui Rodgers, jacqui.rodgers@ncl.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	External pilot results	01/06/2024	25/06/2024	Yes	No
Results article	Economic benefit assessment secondary outcome results	31/03/2025	03/04/2025	Yes	No
Protocol article		28/02/2023	02/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Focus group and interview results thematic analysis	28/05/2025	24/06/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes