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Synopsis

# Adapted Safety Plans to Address Self-Harm and Suicide Behaviours in Autistic Adults: single arm feasibility trial and external pilot RCT

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## Abstract

**Background:** Suicide prevention is a national priority for United Kingdom government policy, and autistic people have recently been identified as a high-risk group in both the Department of Health and Social Care suicide prevention strategy and National Institute for Health and Care Excellence suicide prevention guidelines. No suicide prevention interventions have been developed specifically for autistic people. Safety plans are a simple, cost-effective, potentially life-saving intervention.

**Aims:** 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 a larger future definitive trial is achievable.

**Methods:** Stage 1 involved focus groups with autistic adults (*n* = 15), family members (*n* = 5) and service providers (*n* = 10) to inform adaptations to the Autism Adapted Safety Plans. Stage 2 was an interventional single-arm feasibility trial where autistic adults (*n* = 8) completed an Autism Adapted Safety Plans with a supporter (*n* = 8). Data on recruitment, completion of study measures and participant feedback informed final adaptations to the Autism Adapted Safety Plans and research methods prior to stage 3. Stage 3 was a pilot feasibility randomised controlled trial of Autism Adapted Safety Plans. Autistic adults were recruited via non-National Health Service organisations and self-referral. Participants were randomised without stratification to usual care ± Autism Adapted Safety Plans. The Autism Adapted Safety Plan was completed by the autistic adults with someone trained to support them. Research staff completing follow-up assessments were blind to participant allocation. Primary outcomes were feasibility and acceptability of the Autism Adapted Safety Plans to inform the parameters of a definitive randomised controlled trial. Participants were assessed at baseline, 1 and 6 months.

**Results:** Stage 1 and 2 interviews highlighted the conditions needed to make the process of creating the Autism Adapted Safety Plans acceptable for autistic adults. Stage 2 also informed modifications to recruitment (to include self-referral) in stage 3. In stage 3, 53 participants consented, 49 were randomised to either Autism Adapted Safety Plans + usual care (*n* = 25) or usual care (*n* = 24). Sixty-eight per cent of participants were satisfied with the Autism

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Adapted Safety Plans and 41% rated it as usable. Feedback on the Autism Adapted Safety Plans and study processes employed in the trial were positive with suggested minor adaptations to some outcome measures. Retention of those randomised was 95% at 6-month follow-up. Completion rates for outcome measures were generally high (> 85%). Fidelity ratings for delivery of the Autism Adapted Safety Plans were 94% for therapeutic components and 91% for adherence to content.

**Conclusion:** Autism Adapted Safety Plans are a potentially valuable intervention for autistic adults, provided that the process of creating it is flexible and sensitive to individual needs. The parameters of a future definitive trial of the clinical and cost-effectiveness of Autism Adapted Safety Plans are achievable, with minor recommended adaptations. Further testing of the Autism Adapted Safety Plans to assess its clinical and cost-effectiveness in National Health Service clinical services is urgently needed.

**Limitations:** The sample size was below the initially intended sample of 70 participants due to difficulties with recruitment during the COVID-19 pandemic. As autistic participants self-referred into the study, data are not available regarding how many participants were approached to take part in the study. The majority of the study sample was White.

**Future work:** A full definitive trial testing the clinical and cost-effectiveness of Autism Adapted Safety Plans in National Health Service clinical services is warranted. This fully powered trial will need to recruit a more diverse sample than was possible in the pilot trial. Results suggest that minor adaptations to the Autism Adapted Safety Plans could make this more personalised and accessible, such as through an app or website.

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## Introduction

### *Background*

This report details the work undertaken to establish the feasibility and acceptability of an autism adapted safety plan (AASP) for autistic adults experiencing suicidal thoughts, suicidal behaviours and/or self-harm. It arose from a call commissioned by the National Institute for Health and Care Research (NIHR) Public Health Research programme, focused on suicide prevention intervention in high-risk groups. The study took place between September 2020 and December 2023 in the UK.

Suicide prevention is a national priority for UK government policy, and autistic people have been identified as a high-risk group in the most recent update to the Department of Health and Social Care suicide prevention strategy for England covering the period 2023–8.[1] Autism prevalence in the UK is estimated at 1–2% of the population[2,3] but the most recent psychological autopsy study reported evidence of diagnosed autism and possible undiagnosed autism in around 41% of people who died by suicide in two regions of England.[4] The James Lind Alliance is an independent organisation that brings patients, carers and clinicians together to prioritise research questions for the benefit of health research funders. Two James Lind Alliance priority setting exercises have highlighted an urgent need for research into adapted mental health and suicide prevention interventions for autistic people.[5,6] Overall, this suggests there is an urgent need for tailored suicide prevention interventions for autistic people.

A recent systematic review[7] showed only one other study (aside from the AASP described in this synopsis), which had adapted and tested a suicide prevention intervention in autistic people – Dialectic Behaviour Therapy (DBT).[8] DBT targets various challenges in social interaction, behaviour and emotional regulation to help reduce self-harm, suicidal thoughts and behaviours in a range of clinical groups.[9] These present key areas of difficulty for many autistic people, and have been shown to contribute to their risk of self-harm, suicidal thoughts and behaviours. One randomised controlled trial (RCT) showed that DBT significantly reduced suicidal ideation and suicide attempts in autistic adults compared to treatment as usual at end of treatment, but this difference did not remain at 12-month follow-up.[8] This suggests that DBT may be an effective short-term treatment for self-harm, suicidal thoughts and behaviours in autistic adults. However, further research is needed to explore other interventions which could be delivered with minimal training, in a wider range of contexts including outside health/clinical contexts (i.e. public health contexts), and over a longer period of time.

Safety plans are a simple, scalable, suicide prevention intervention that can be personalised, with demonstrated effectiveness in a range of clinical groups[10,11] and specifically recommended as an appropriate intervention for autistic people.[12] Safety plans consist of a prioritised list of hierarchical steps that can be used prior to or during a crisis to mitigate risk of self-harm and suicidal behaviour. The original Stanley and Brown suicide safety plan involves the identification of: (1) Warning Signs;

(2) Internal Coping Strategies; (3) Social Contacts and Locations; (4) Family Members or Friends that may offer help; (5) Professionals or Agencies to help; and (6) How to Keep the Environment Safe.[13] The concrete steps involved in formulating the safety plan may be particularly suitable for autistic thinking styles, and support identifying warning signs of approaching crisis, which may in turn help autistic people to recognise they are in crisis at an earlier point.[14,15] Safety plans could help support autistic people to develop personalised strategies, rehearse strategies for seeking help, and restrict access to lethal means of self-harm. Thus, safety plans are one of the most promising interventions to prevent suicide among autistic adults.

However, evidence suggests that interventions designed to be administered to non-autistic people require modification to meet the thinking and communication styles of autistic people and the unique challenges faced by autistic people. Assessments and interventions need to be clear, provide support and training for engaging with content relating to expression of emotions and appropriately capture the presentation of mental health conditions in autistic people.[16–19] Furthermore, providing the evidence base for the introduction of novel clinical tools involves being able to establish whether it is feasible and acceptable to undertake the rigorous testing required in a RCT, including accurate assessment of clinical and economic outcomes.[20] Thus, the current study aims to develop adapted suicide safety plans with and for autistic adults and establish the parameters of a future definitive trial of the clinical and cost-effectiveness of AASP.

## *Objectives*

The aims of this study were to evaluate the feasibility and acceptability of the use of AASP for autistic adults, and to undertake an external pilot RCT to explore whether the components of a larger future definitive trial are achievable. Shown in *Figure 1*, this study comprised three stages with the following objectives: (1) an intervention refinement to ensure that our AASP is suitable for autistic adults (stage 1); (2) an interventional single-arm trial of feasibility and acceptability (stage 2) to explore data collection tools/methods and gather information to inform stage 3; and (3) an external pilot RCT of the AASP (stage 3) to inform a future definitive trial, including recruitment, randomisation, outcomes measures, treatment, follow-up assessments and economic evaluation methods/tools. As shown in *Box 1*, Goodwin *et al.* describe the adaptations of the safety plan for autistic adults

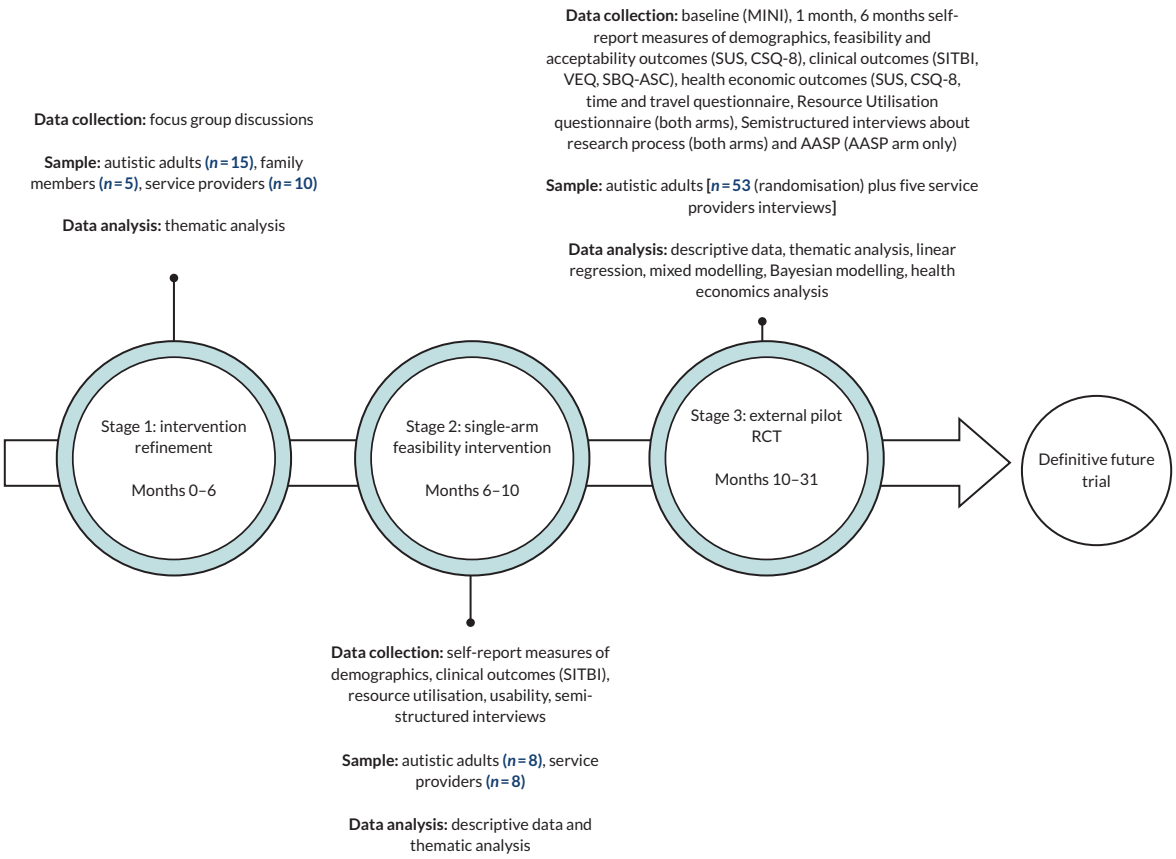


**FIGURE 1** Study pathway diagram: AASP. CSQ-8, Client Satisfaction Questionnaire-8; MINI, Mini-International Neuropsychiatric Interview; SBQ-ASC, Suicidal Behaviours Questionnaire – Autism Spectrum Conditions; SITBI, Self-Injurious Thoughts and Behaviours Interview; SUS, System Usability Scale; VEQ, Vulnerable Experiences Questionnaire.

**BOX 1** Published papers resulting from the study

Bhattarai N, Goodwin J, Pelton M, Gordon I, Rodgers J, Cassidy S, *et al*. Health economic evaluation of autism adapted safety plans: findings on feasibility of tools from a pilot randomised controlled trial. *BMC Health Serv Res* 2025;**25**:473. https://doi.org/10.1186/s12913-025-12642-8

Rodgers J, Cassidy S, Pelton M, Goodwin J, Nielsen E, Wagnild J, *et al*. Feasibility and acceptability of autism adapted safety plans: an external pilot randomised controlled trial. *EClinicalMedicine* 2025;**84**:103260. https://doi.org/10.1016/j.eclinm.2025.103260

Goodwin J, Gordon I, O'Keeffe S, Carling S, Berresford A, Bhattarai N, *et al*. Adapting safety plans for autistic adults with involvement from the autism community. *Autism Adulthood* 2025;**7**:293–302 https://doi.org/10.1089/aut.2023.0124

Rodgers J, Goodwin J, Nielsen E, Bhattarai N, Heslop P, Kharatikoopaei E, *et al*. Adapted suicide safety plans to address self-harm, suicidal ideation, and suicide behaviours in autistic adults: protocol for a pilot randomised controlled trial. *Pilot Feasibility Stud* 2023;**9**:31. https://doi.org/10.1186/s40814-023-01264-8

(stages 1 and 2).[21] Rodgers *et al*. describe study methods and analytic strategy for the pilot RCT (stage 3).[22] Main results of the pilot RCT (stage 3) are described in Rodgers *et al*.[23] Feasibility of assessing health economic outcomes (stage 3) are described in Bhattarai *et al*.[24] This section describes detailed objectives of each paper within the overall study framework and gives an overview of study methods and key results.

### *Stages 1 and 2: intervention refinement and single-arm intervention trial*

Adapting safety plans for autistic adults with involvement from the autism community.[18]

## Detailed objectives

The aim of the focus groups (stage 1) and interviews (stage 2) was to seek advice from autistic adults and those who support them (family members and service providers) on how to adapt safety plans for autistic adults.

## Methods

In stage 1, researchers conducted focus groups with autistic adults ($n$ = 15), family members ($n$ = 5) and service providers ($n$ = 10), about their views of the AASP. In stage 2, researchers conducted interviews about the acceptability of the AASP with autistic adults who had developed an AASP ($n$ = 8) and service providers who had supported them ($n$ = 8) in the interventional single-arm feasibility trial. Interview and focus group transcripts were analysed using thematic analysis. See *Appendix 1*, *Table 2* for a summary of protocol amendments.

## Results summary

Two themes were found: (1) creating the right conditions for safety planning; and (2) creative process to be flexible and evolving.

### *Creating the right conditions for safety planning*

Theme one highlighted conditions needed to make the process of creating the AASP acceptable and 'reassuring' for autistic adults. This included creating the AASP with someone the autistic adult could trust and at the right place and time, when they were not distressed or in crisis. It was common for participants to describe negative experiences in social relationships including when accessing healthcare services where '*you feel like you're not being believed and one of the worst things you can do to an autistic person is not believe them*'. This had led many participants to feel continually let down, rejected or betrayed and therefore mistrustful in relation to seeking help or sharing their experiences of suicidality. Therefore, a supporter who '*takes an interest in you, a real interest and doesn't just drop you in it afterwards*' with the right skills and qualities throughout the development of a safety plan was needed for an autistic person to feel comfortable enough to fully open up.

### *Creative process to be flexible and evolving*

Theme 2 described the need for safety planning to be a creative, flexible, and iterative process. Findings revealed that autistic adults may need help in '*thinking about plan more before doing it*' to assist with expressing their emotions and identifying coping strategies, supported through visual resources and suggestions from the service provider. It also emerged that creating a safety plan might be more engaging for some autistic people if autistic people and service providers had knowledge of what safety plans were and what was required to create them before AASP appointments. During appointments, fluctuating capacity could affect progress depending on what was happening in the person's life or environment at the time so that '*when you're in that state and someone asks you something you can't tell them*'. This needed to be recognised while developing the AASP and revisited in further appointments if appropriate. To ensure the AASP is accessible in times of crisis, it also needed to meet the autistic adults' preferences in terms of formatting, for example different versions for different situations (e.g. crisis, simplified) or prompts to use it and how it is stored (i.e. hard copy or electronic).

### *Stage 3: pilot randomised controlled trial: method*

Adapted suicide safety plans to address self-harm, suicidal ideation, and suicidal behaviours in autistic adults: protocol for a pilot RCT.[19]

## Detailed objective

The overall objective of the protocol paper[22] was to specify a priori all study processes and data analytic strategy for the stage 3 (as shown in *Figure 1*) pilot RCT of the AASP (ISRCTN70594445).

## Methods and procedure for pilot randomised controlled trial

Autistic adults with experience of self-harm, suicidal thoughts and behaviours within the past 6 months were recruited via non-NHS services (charities, higher education and third-sector organisations) and via self-referral route promoted through social media announcements. Inclusion criteria were: (1) a formal diagnosis of autism; (2) accessing services via social care or third-sector organisation or self-reported; (3) self-reported self-harm, suicidal thoughts or behaviours within the last 6 months; (4) sufficient English language fluency to complete the safety plan; and (5) aged over 18. Insufficient English language fluency and current psychotic symptoms were exclusion criteria.

Interested individuals completed an expression of interest form granting permission for the research team to make contact to provide more information. Individuals who self-referred were linked to a support worker from a partner organisation or completed the AASP with a researcher. Data consent, data collection and completion of the safety plan took place via telephone or video call to meet the access preference of the participant. Training for support workers and researchers was co-designed with autistic people and included information about suicide and self-harm in autistic people, adaptations from standard safety planning, considerations when working with autistic people, helpful insight into autism, such as the double empathy problem (where autistic and non-autistic people find it difficult to communicate, understand and empathise with one another),[25] and gave opportunities to discuss and practise the AASP. Participants completed baseline assessments (*Table 1*) and were then randomised to receive either the AASP in addition to usual care or usual care only, on a one-to-one basis without stratification. Randomisation was done via Sealed Envelope (www.sealedenvelope.com) facilitated by an unblinded researcher who informed participants of their randomisation status. The unblinded researcher did not undertake follow-up assessments or data analysis. With consent AASP completion was audio recorded to determine fidelity. Serious adverse events (SAEs) were captured for participants, none were expected, so all SAEs were classed as unexpected. Follow-up assessments were undertaken at 1 and 6 months with a full list of measures administered at each time point detailed below:

### *Stage 3: pilot randomised controlled trial: main results*

Autism adapted safety plans: an external pilot RCT.

#### Detailed objective

The overall objective of this paper[23] was to describe the results of the stage 3 (as shown in *Figure 1*) pilot RCT of the AASP (ISRCTN70594445). Primary feasibility and acceptability outcomes and secondary clinical outcomes are described here. The AASP and resource pack is available here (https://sites.google.com/view/mentalhealthinautism/resources/safety-plan).

## Results summary of the pilot randomised controlled trial of the Autism Adapted Safety Plans

Forty-nine participants were randomised to either AASP + usual care ($n$ = 25) or usual care ($n$ = 24). One participant in the AASP arm was lost to contact after randomisation; all participants were retained in the usual care arm. All retained participants randomised to the AASP completed a safety plan. Completion of the outcomes measures was high; 92% and 96% of participants in the AASP and usual care arms, respectively, completed assessments at the 6-month follow-up.

Twenty-two participants in the AASP arm completed an assessment of the intervention's usability using the System Usability Scale (SUS). Scores on the SUS can range from 0 to 100, with higher scores indicating better usability. The mean SUS score was 61.2 [standard deviation (SD) 20.5; range of 19–96]. Nine respondents (41%) reported a score of 68 or higher, indicating satisfaction with usability. Satisfaction with the AASP was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8). Possible CSQ-8 scores range from

**TABLE 1** Time points at which data were collected during stage 3

| Procedure | Screening | Baseline | 1-month follow-up (F1) | 6-month follow-up (F2) |
|---|---|---|---|---|
| ***Autistic adults and professionals*** | | | | |
| Eligibility checklist | X | | | |
| Informed consent | X | | | |
| Well-being plan (to note adaptations, participant safety, and emergency contact) | X | | | |
| ***Autistic adults only*** | | | | |
| Demographics[a] | | X | | X |
| MINI | | X | | |
| SITBI | | X | X | X |
| VEQ[b] | | X | X | X |
| SBQ-ASC | | X | | X |
| EQ-5D-5L | | X | | X |
| Resource Utilisation Questionnaire | | X | | X |
| Time and Travel Questionnaire | | X | | X |
| Randomisation[c] | | X | | |
| Acceptability and feasibility semistructured interview for autistic adults | | | | X |
| SUS | | | | X[d] |
| CSQ-8 | | | | X[d] |
| ***Professionals only*** | | | | |
| Acceptability and feasibility semistructured interview for professionals | | | | X |

EQ-5D-5L, EuroQol-5 Dimensions, five-level version; MINI, Mini-International Neuropsychiatric Interview; SBQ-ASC, Suicidal Behaviours Questionnaire – Autism Spectrum Conditions; SITBI, Self-Injurious Thoughts and Behaviours Interview; VEQ, Vulnerable Experiences Questionnaire.
a Demographics to include – socioeconomic status, employment, housing, access to support, physical health, and education.
b At baseline, this questionnaire asks about their entire life. At F1, it asks about the past month. At F2, it asks about the past 5 months.
c Randomisation to take place following completion of baseline assessment.
d Only completed by participants allocated to the AASP arm.

0 to 32, with higher scores indicating greater satisfaction. Of the 19 AASP participants who completed the CSQ-8, the mean score was 24.8 (SD 6.5; range 10–32). Thirteen respondents (68%) indicated they were satisfied with the intervention based on a CSQ-8 score > 20.

The Self-Injurious Thoughts and Behaviours Interview (SITBI) questionnaire was used to measure changes in the occurrence and future likelihood of several self-injurious thoughts and behaviours, including suicidal ideation, suicide plans, suicidal gestures, suicide attempts and non-suicidal self-injury. There was a significant difference between arms in the likelihood of making a future suicide plan at 1 month {mean difference −1.00 [95% confidence interval (CI) −1.90 to −0.18], Cohen's $f^2$ 0.38} and 6 months [mean difference −1.00 (95% CI −1.80 to −0.19), Cohen's $f^2$ 0.25] after adjustment for baseline values, age and gender. There was no difference in likelihood scores or occurrences for the other SITBI domains, although it is important to note that this trial was not designed or powered to detect differences in any outcomes between trial arms. Suicidal behaviours and negative life experiences were measured at multiple time points using the Suicidal Behaviours Questionnaire – Autism Spectrum Condition[26] and Vulnerable Experiences Questionnaire,[27] respectively. No differences in these outcomes were observed between trial arms.

To identify which sociodemographic characteristics might be important stratification variables in future definitive trials, adaptive least absolute shrinkage and selection operator (LASSO) models were used to explore associations between multiple characteristics (income, education level, employment status, housing arrangement,

physical health status and service access) and occurrences of five self-injurious behaviours (measured by the SITBI) at 6 months. Variables whose coefficients were not forced to zero were considered potentially important. Broadly speaking, education level and employment status were most consistently retained in the adaptive LASSO models: higher educational levels and self-employment (vs. full-time employment) were associated with lower likelihoods of self-injurious behaviours. This suggests education level and/or employment status may be important stratification variables in future definitive trials.

Forty-seven interviews were undertaken with participants after the completion of the 6-month follow-up to assess the accessibility and acceptability of: (1) the research process (both arms); and (2) completing the AASP (AASP arm only). There were three main themes in participants' *feedback on the research process*: (1) study information was acceptable but managing participants' expectations fully required more detailed information about what safety planning was because 'it's not super clear like how easy is the safety plan is to use and follow and things like that' or what to expect in AASP appointments and alternative options if the AASP was not suitable; (2) a flexible and positive autism adapted research process was perceived, where 'any suspiciousness … about autism research was … being chipped away'. This was despite the language of questions often being seen as ambiguous or ill-fitting with their conceptualisation of suicidality because "some terms didn't refer to my specific idea that I had in my head' and questions such as 'how would you know whether it was the most lethal attempt or not?' arose; and (3) perceived gains from taking part in the research included 'validation, contribution and connection' from increased self-understanding and self-expression.

There were three main themes in participants' *feedback on the* AASP: (1) varying degrees of preparation work 'something along the lines of … do you do you know what these feelings are?' was needed by participants for AASP appointments '… because it's a social disability, this is how you build up those tools for someone'; (2) essential features of the cocreation process were flexibility, 'human touches' and that participants 'instinctively trusted' their supporters so they were 'joined in the activity … we built a personal history' to produce authentic and personalised content; and (3) the AASP was 'better than what the mental health team had' and most useful with meaningful content, an accessible format and different versions for different situations.

In the AASP arm, there were three SAEs impacting three participants and there were eight Events of Special Interests impacting five participants. In the control arm, there were 9 SAEs impacting 5 participants and 16 Events of Special Interests impacting 11 participants. None were related to study participation.

### *Stage 3: pilot randomised controlled trial: health economic evaluation*

Health economic evaluation of intervention aimed towards autistic people: findings on feasibility of tools from a pilot RCT.[24]

## Detailed objective

The overall objective of this paper was to describe the feasibility of collecting data on resource utilisation and outcome measures and conducting a health economic evaluation of the AASP intervention targeted towards autistic people in a future definitive trial.[24]

## Methods for the health economic evaluation

The economic evaluation involved the following key stages:

1. Pre-testing tools to assess their appropriateness and their refinement.

We developed a bespoke or adapted resource use questionnaire, time and travel questionnaire, a contingent valuation (CV) survey,[28] a standard gamble,[29] and a time trade-off[29] questionnaire for use with autistic adults in the study settings. EuroQol-5 Dimensions, five-level version (EQ-5D-5L)[30] and EuroQol-5 Dimensions visual analogue scale (EQ-5D-VAS)[29,31] were also considered. In addition, we also considered whether a Discrete Choice Experiment (DCE)[32] could be used as a tool to assess the trade-offs that autistic adults make when considering the characteristics of an intervention along with what this could tell us about the potential uptake of the AASP intervention. These tools were discussed in focus groups consisting of autistic adults and researchers/experts in the autism related research, to establish their appropriateness (including ease of use, sensitiveness considering the participants) in the study population. Tools considered worthy for further exploration following the focus group discussions were pre-tested. The CV method, resource use questionnaire, time and travel questionnaire, EQ-5D-5L and EQ-5D-VAS were pretested to explore their comprehension and ease of completion in a small sample of autistic adults. The feedback from the pre-test was utilised to refine the questions in these tools.

2. Evaluating response rates and completeness of data collection tools.

Based on feedback the resource use questionnaire, time and travel questionnaire, and the EQ-5D-5L including the EQ-5D-VAS, were considered worth further exploration of their feasibility, and were developed into a survey instrument and administered to participants over the telephone (by interviewer reading out the questions) or sent out via e-mail in both arms of the pilot trial at baseline and at follow-up (6 months). The response and completion rates for these tools were assessed at baseline and follow-up to demonstrate the feasibility of conducting an economic evaluation using data from these tools. In addition, the responsiveness of EQ-5D-5L as a generic health outcome measure in the autistic people was also assessed by analysing the changes in the percentage of participants reporting some problems in each of the domain of EQ-5D-5L. The study was not powered to detect differences in resource utilisation or health outcomes; therefore, the resource utilisation and health outcome data were not used to conduct a cost-utility analysis.

## Results summary of the health economic evaluation

- Standard gamble and time trade-off were deemed to not be appropriate tools to measure generic health outcomes in autistic adults already with suicidal ideation and instances of self-harm.
- CV and DCE were deemed not to be appropriate, as these tools have heavy cognitive burden in an autistic population where a majority are dyslexic.
- Completion rates for resource utilisation and time and travel questionnaire, and EQ-5D-5L were good indicating that it would be feasible to collect resource use and health outcomes data using these tools in a definitive full-scale RCT. However, there is not sufficient evidence from this study to show EQ-5D-5L would be responsive in autistic adult population.
- Suggestions for improvements in completion rates of questions such as EQ-5D-VAS could be enhanced including guidance on scoring them.
- Number of items not completed on the resource use questionnaire (e.g. medication use) is likely to be because of the participants found it hard to recall the details, coupled with their commitment to provide only accurate answers and not because of poor understanding of the questions.
- The results of the feasibility assessment of the health economic evaluation tools provide the information for an economic evaluation conducted as part of a prospective full-scale RCT.



## Discussion

The primary aim of the study was to establish the feasibility and acceptability of the AASP and inform the parameters of a definitive RCT. The secondary aims were to explore the extent to which clinical and health economic outcomes can be accurately measured and reported in a future trial. The study comprised of three stages. The objective of stage 1 (Intervention Refinement) was to refine the AASP in partnership with autistic adults and those who support them. Thirty-four people participated in the online focus groups and the objectives of this stage were fully met. Stage 2 comprised an interventional single-arm feasibility trial to explore data collection tools/methods and gather information to inform the subsequent external pilot RCT. All of the objectives of stage 2 were met.

Stage 3 comprised an external pilot RCT to gather key data to inform a definitive trial. In order to determine whether progression to a full trial was warranted we evaluated performance against key progression criteria including the number of participants who completed the assessments at the primary end point; the percentage of participants who rated the usability of the AASP on the SUS as 68 or above, at the primary end point; the percentage of participants who reported satisfaction with the AASP (indicated as a score > 20 on the CSQ-8) at the primary end point and fidelity of delivery to the AASP to the manual. We recruited 53 autistic adults during stage 3. Forty-nine were randomised and 47 (95%) were retained to 6-month follow-up. Sixty-eight per cent of participants in the AASP arm were satisfied with the AASP, but only 41% rated it as usable on the SUS. However, we have some concerns about the suitability of the SUS as an outcome measure to determine usability with autistic adults. The SUS was developed for use with the general population, not autistic people and prioritises ability to complete an intervention independently and quickly as positive indicators of usability. As such, these ratings were low for our participants. However, in contrast during the

feasibility interviews autistic participants reported that an important and valued aspect of the usability of the AASP was the opportunity to access to support and flexibility in relation to the number of sessions needed to complete the AASP. A future definitive trial should explore a more appropriate measure to assess usability in the context of supporting autistic people to complete AASPs. Completion rates for outcome measures were generally high (> 85%), and fidelity ratings for delivery of the AASP were excellent overall: 94% for therapeutic components and 91% for adherence to content. Taken all of this into account, study progression criteria were largely met, and where they were not (i.e. usability based on the SUS, alternate methods indicated) suggesting that the parameters of a future definitive trial of clinical and cost-effectiveness of AASP to reduce self-harm and suicidal behaviours in autistic adults are achievable. Overall, this study has laid a strong foundation for a larger RCT to further evaluate the effectiveness of the AASP in reducing self-harm and suicidal behaviours in autistic adults. The positive feedback and excellent retention and completion of outcome measures are promising indicators for the feasibility of such a trial. However, further refinement of the AASP and outcome measures is warranted for future work.

Our study contributes significantly to the limited knowledge on suicide prevention interventions for autistic people. There have been no previous pilot or definitive trials of suicide safety plans for autistic adults. Our findings are the first to indicate that AASPs are acceptable and feasible for autistic people and have the potential for reducing autistic adults' high risk of self-harm and suicidal behaviour. Some previous work has indicated that clinicians do aim to use safety plans for autistic people but lack confidence in using safety plans with this group. This finding supports our observation that support workers require training to enable them to adequately support autistic people experiencing crises.

Our study had a number of strengths. Patient and public involvement (PPI) and coproduction were key and foregrounded at all stages of the study ensuring that the study design, materials and methods were acceptable and inclusive. Retention of consented participants was excellent across both arms of the trial. Only two withdrawals occurred during the study. Feasibility interviews indicated that a main reason for this high retention rate was participants willingness to help others through the study, even in the case of not receiving the AASP intervention themselves, or if the AASP intervention did not work for them. Completion rates for baseline and outcome measures were also very good. Fidelity of delivery of the AASP was excellent ensuring that the intervention was implemented consistently and accurately.

It is also essential to acknowledge the challenges and limitations faced during our study. The study began in September 2020, during the ongoing COVID-19 pandemic, which had a significant impact on research activities and procedures. A number of changes to the study procedures were therefore necessary in order to enable the study to continue. First, the smaller sample size of 53 (below the initial target of 70 participants) was due to difficulties with recruitment during the COVID-19 pandemic. We encountered significant difficulties in recruiting autistic participants and their linked support workers through partner organisations in stage 3. Over the 14 months recruitment window, recruitment rates fluctuated widely month to month (between 0 and 14). However, based on our results a recruitment target of three participants per month would be achievable in a future trial. There is no recommended minimum number of participants for a pilot or feasibility study, as the aim is not to estimate a target difference in relative effectiveness but to address outcomes to estimate the parameters for a future trial. Therefore, the reduced number of participants likely did not affect our primary aim to estimate the parameters for a future trial to test clinical and cost-effectiveness of AASP.

While the exact nature of these difficulties is challenging to determine, it is likely that the pandemic played a substantial role. Many partner organisations reduced their operations and furloughed staff during 2020–2. In response to these difficulties and following advice from our Lived Experience Advisory Panel (LEAP) the self-referral route was introduced. This allowed autistic participants to directly enrol in the study. A knock-on effect of this necessary change to recruitment strategy is that data are not available regarding how many autistic participants were approached with an invitation to take part in the study, compared to how many of these participants consented to take part. Additionally, due to the pandemic-related restrictions, the original plan to train staff from third-sector and non-NHS partner organisations to support autistic individuals in developing an AASP was adapted from face-to-face delivery of training to remote delivery. The training methods were adapted to enable them to be delivered via an on-line platform over the course of two 3-hour workshops, with a pre-recorded preparatory slide set. This modification was well-received by partner organisations, and over 100 staff accessed the training during stages 2 and 3. This adaptation potentially increased the reach of the training enabling it to be delivered to services and individuals who would not have been able to attend for the face-to-face sessions.

It is also important to reflect on additional reasons for challenges to recruitment through third-sector organisations. Despite over 100 staff accessing the training during stages 2 and 3 of the study, only a small number of service providers supported autistic people to complete a safety plan in stage 3, with a majority of autistic participants recruited through self-referral. One possible reason for this aside from the challenges posed by the COVID pandemic, and which was raised informally in discussions with organisations, was the issue of randomisation. Specifically, organisations and service providers did not feel that they could invite autistic people they support to the study when there was a chance that they might not receive a much-needed intervention. We also received informal feedback that despite not taking part in the research study, organisations and service providers used the training in their practice to better adapt their existing safety planning work with autistic adults coming into contact with their service. This indicates that although the training and AASP were valued by organisations and service providers supporting autistic people, these third-sector organisations may not have found randomisation an acceptable research method. However, our results also suggest that autistic adults who self-referred to the study did find the research methods including randomisation acceptable. A future fully powered trial may need to change recruitment avenue to include NHS services, where clinicians and services are more set up to deliver RCTs, and/or consider a waitlist RCT design.

It was also necessary to introduce remote data collection and AASP delivery due to the COVID-19 pandemic to enable the study to continue and to comply with COVID-19 restrictions and prioritise the safety of participants and staff. Many factors had to be taken into consideration, such as data protection for the participants and supporters, the use or potential limited use of technology and any associated costs and whether delivering the assessments and AASP online would be safe, feasible and could be delivered with fidelity. As both the assessment and AASP had been designed to be delivered in a face-to-face format the materials had to be reviewed to ensure that they could be delivered in an on-line format and some adjustments needed to be made to the materials.

The move to online delivery of the study also had some benefits. Once initial technological challenges were overcome some participants reported that it was easier for them to participate online as this reduced stress and the time commitment required because they did not need to travel to/from appointments. This enhanced convenience may have facilitated increased participant engagement and satisfaction and retention. Remote delivery also greatly extended the geographical reach of the study across England and Wales. Additionally, it was also easier to offer appointments over multiple sessions to allow for more complete data collection and to reduce pressure on the participants to be available for a lengthy phone call. The opportunity to develop an AASP across several sessions was highlighted by a number of participants as a strength of the methods.

## Patient and public involvement

### *Aim*

The aim of the PPI embedded within the study was: (1) to scope, describe and implement changes to a suicide safety plan to better meet the preferences of autistic people; and (2) to determine if a pilot RCT of the AASP is meaningful and accessible for autistic people. PPI was essential to this project given evidence that the way that suicide research has been carried out has led to measures and models that do not accurately describe the experiences of autistic people.[33,34]

### *Methods*

Patient and public involvement methods and activities to achieve these aims included (1) several autistic people were co-applicants and members of research staff; (2) a LEAP of up to 11 autistic adults provided guidance and consultation at all stages of the project; (3) 6 focus groups included autistic adults, service providers and family members (stage 1); (4) 16 feasibility and acceptability interviews were conducted with autistic adults and service providers in the single-arm intervention trial (stage 2); (5) 47 feasibility and acceptability interviews were conducted with participants after 6-month follow-up in the pilot RCT (stage 3); (6) a dissemination committee comprised of members of the autism community; and (7) an anonymous survey to the advisory group members to capture impact of participation in the LEAP.

### *Results*

Impacts included: (1) autistic lived experience reflected in study decisions, (2) refinements to the safety plan, particularly recommendations of support with naming emotions, changes to presentation to meet autistic thinking and communication preferences, (3) changes to research process for stage 3 to better meet autistic accessibility preferences and information to inform feasibility and acceptability of a future definitive trial. The LEAP informed study materials, study recruitment via self-referral, removed inappropriate health economic measures, recommended how to keep in touch and support study retention and supported researchers to

consider how to describe the project and support people to take part. Outcomes included meeting recruitment targets, retaining participants within the study and overall report of feasibility and acceptability of AASP. Via the survey, advisory group members reported that taking part was a positive experience due to contributing to better outcomes for autistic people, learning about autism, connecting with others.

### *Discussion and conclusions*

Patient and public involvement impacted all stages of the study from project inception and detailed design to implementation and dissemination. Impacts on researchers and LEAP members were largely positive. This is consistent with research describing potential impacts of PPI at all research stages and extends typical PPI involvement in clinical trials.[35] This is in line with research describing that working in partnership with autistic people is necessary to ensure research processes are accessible[36] and that suicide prevention interventions are effective.[6] Positive impacts reported by advisory group members reflect research describing broader benefits of taking part in research for those with lived experience of self-harm.[37] Overall, PPI played a critical role in developing the AASP and designing, delivering and disseminating a study accessible to autistic people that meets the rigorous requirements of a pilot RCT.

### *Reflections/critical perspective*

Strengths of PPI in this study are the significant impacts reported, and positive project outcomes that resulted from PPI. PPI was designed throughout the study in line with good practice recommendations. Recommendations from the LEAP included tightening ground rules for meetings and more tightly sticking to an agenda. Future studies could consider co-producing ground rules in a future study. Despite these benefits there is an identified lack of diversity among the PPI contributors, with an under-representation from individuals from non-White ethnicity. Similarly, PPI contributions were, by necessity largely as a consequence of procedural changes resulting from COVID 19, restricted to those who were computer literate and comfortable participating in on-line consultation and meetings. Future research should endeavour to include PPI contributions from autistic people from diverse backgrounds.

## Equality, diversity and inclusion

In this study, 49 autistic adults participated recruited from third-sector organisations and by self-referral in England. Despite the move to remote delivery increasing the reach of the study and enabling recruitment from a large geographical area, the sample was not representative of the ethnic diversity across the UK. The overwhelming majority of participants were from White ethnic backgrounds. A total of 6% ($n$ = 3) of participants in this study identified as non-White. This is consistent with research indicating that there is a need for more culturally responsive practices for autistic people. We are not aware of any published data on UK ethnicity groupings specifically for autistic people experiencing suicidal thoughts, behaviours and/or self-harm, to ascertain whether or not our participants were a representative population, however it seems unlikely that this would be the case. There is inconsistent evidence about the prevalence of autism in a range of ethnic communities[38] and disparities in UK racial and ethnic autism diagnoses.[39] Autism diagnosis is influenced by ethnicity as well as socioeconomic status and living location.[40] It is also substantially affected by age related differences in proportions of people diagnosed.[41] For example, recent figures show that around 1.8% of school children in England are autistic, with prevalence highest prevalence among Black school children of around 2.1%.[42] This recent, sharp increase of diagnoses among Black UK school children suggests a likelihood of a historical and significant underdiagnosis which is reflected in our adult sample.

Existing evidence together with consultations with non-White researchers and people with lived experience of autism and suicide prevention indicates that our low recruitment of non-White groups is likely to have been influenced by a combination of factors. These include that: Autism is not officially recognised in some communities nor is accessing services; professionals perceive autism differently and racial stereotypes can therefore be problematic with a diagnosis (e.g. 'he is Black so he can't have autism, it must be something else'); a concern among ethnic groups about stigma about both autism and suicidality either in the general population or by providers; a lack of engagement with mental health services due to personal and environmental reasons (e.g. an inability to recognise and accept mental health problems); factors affecting the relationship between the service user and healthcare provider[43] for example a perception among non-White groups that third-sector services are not 'made for them' and they are not listened to or understood; a hesitancy to participate in studies that identify them as autistic or due to a fear of misunderstanding or maltreatment by researchers;[44] socioeconomic status and lack of incentive to take part; difficulties accessing the internet to hear about or participate in online research; study information not reaching more diverse groups due to different social media platforms; study materials depicting White RAs on the info sheet and assuming it's 'not for me'; lack of privacy to take part (e.g. adults living with parents until marriage).

To try to increase diversity in our sample we carried out the following activities: We adopted an inclusive approach to recruitment, with national reach through our third-sector partners. During recruitment we explored potential reasons why autistic people from non-White backgrounds were under-represented, and adapted recruitment policies accordingly. This was informed by a scoping review of the literature on engagement and inclusion of ethnic groups in autism and mental health research. Autism organisations already partnered with the study and known contacts of the research team were contacted to recruit non-White advisory group members. We also sought advice from non-White researchers known for their expertise in autism and/or suicide research with non-White communities. To increase the potential for a more ethnically diverse sample, they communicated study information to non-White groups engaged in their research to whom they were known and trusted, via specific social media groups and online workshops. In addition to these activities our research team comprised of individuals from a range of cultural and ethnic backgrounds, as well as those with lived experience. However, despite these efforts the representation of autistic people from non-White backgrounds in our sample remains poor. Future research should continue to actively explore any potential reasons why autistic people from non-White backgrounds are under-represented and promote recruitment policies that aim to rectify this imbalance and incorporate issues relating to diversity into research questions.

The study sample was also not necessarily representative of the autism population generally. However, the high rates of low income, non-binary gender and late diagnosis of autism may actually be representative of autistic people at higher risk of self-harm and suicide. Recruitment methods via self-referral and support organisations and the requirement to participate in online methods means that our sample was comprised of autistic adults with a relatively high level of IT literacy and access to the means to participant in this way, which may not be representative of the wider population.

Our research team comprised of individuals from a range of cultural and ethnic backgrounds, as well as those with lived experience.

## Impact and learning

There are a number of valuable learning opportunities and positive outcomes that have emerged from the study which indicate the broader impact of the research beyond the immediate study objectives and will inform both future research work and clinical practice. The study has provided an opportunity to ascertain essential insights into the preferred form, structure, and format of safety plans to ensure that they are accessible and inclusive for autistic individuals. This knowledge can guide future research and clinical practice, ensuring that safety plans are more effective and tailored to the needs of this population.

Valuable feedback and advice received from LEAP collaborators and autistic participants has been instrumental in assessing the usability and suitability of a range of clinical and health economic outcome measures. This feedback will be critical in shaping future studies, not only related to this topic but more broadly as well.

A key deliverable from the study is the development and implementation of support worker training on how to support autistic people to develop an AASP. This training package was completed by over 100 support workers from a range of third-sector organisations and feedback from the training was overwhelmingly positive. No such other training currently exists, and the package will be available as a standalone resource for future delivery across both clinical and research settings.

The research staff involved in the study benefitted from training on a range of clinical measures and research and statistical techniques and some have now progressed to clinical training and others to research posts. Opportunities were provided for undergraduate students and trainees to work as interns during the study gaining valuable skills and knowledge, to further their career prospects.

## Implications for decision-makers

The Department for Health and Social Care Suicide Prevention Strategy (2023–8)[1] highlighted an urgent need for suicide prevention interventions designed with and for autistic people to reduce the high risk of suicide in this group. Our study is the first to address this priority, being the first study to report on the feasibility and acceptability of AASP to reduce risk of self-harm and suicidal behaviour, developed with and for autistic adults. Our data support evidence from other work exploring mental health issues with autistic people that assessment and interventions need to be adapted to the needs of autistic people in a flexible and inclusive way. The results indicate that adapted safety plans are feasible and acceptable to autistic adults. There are a number of implications for clinical practice and decision makers, specifically:

- AASP is acceptable to most autistic adults and should be offered via clinical services.
- Clinical and support staff should receive specific training on how to support an autistic person to develop a safety plan.
- Autistic people may benefit from the support of someone who is familiar to them and/or has knowledge of autism whil completing their safety plan.
- Safety plans may need to be offered in a range of different formats.
- Support may be helpful to enable autistic people to access and describe their feelings while developing their safety plan.

## Research recommendations

We have identified a number of questions for future research and have indicated the area of research to which they relate below. We suggest that a more formal process of consultation with the autism community should be undertaken to determine research priorities.

### *Safety plans*

Our study indicates that AASPs are acceptable to autistic adults who have experienced self-harm, suicidal thoughts and/or behaviours, and that they are feasible to deliver. Our study was not a fully powered trial and so we cannot draw any conclusion regarding the clinical and cost-effectiveness of the AASP. Our study also provided evidence in terms of feasibility and acceptability of study design and outcome measures. A definitive trail of the AASP is now warranted.

### *Further interventions for suicide and self-harm*

Our study also indicates that the AASP is not for everyone and that for some autistic people an alternative approach to self-harm and suicide prevention may be more acceptable. Future work should investigate into what other kinds of interventions might be acceptable and effective with and for autistic people.

### *Identification and prevention of self-harm, suicidal thoughts and/or behaviours with autistic young people*

Our study included autistic people aged 18 years and over. Sadly, there is increasing evidence of the prevalence of self-harm and suicidal thoughts and behaviours for autistic children and young people. Future research could explore the feasibility and acceptability of the AASP with this group.

### *Autistic people's perspectives on their experiences of self-harm, suicidal thoughts and/or behaviours*

Our data provide further evidence that autistic people's experiences of suicide and self-harm may not be experienced and present in the same ways as those of non-autistic people. Developing a nuanced and detailed understanding of these experiences is critical to the further refinement of both assessment and intervention techniques designed to support autistic people experiencing distress. Specifically, research should focus on developing an understanding of how autistic characteristics interact with the experience of self-harm, suicidal thoughts and behaviours.

## Conclusion

We reported the results from the first pilot RCT exploring feasibility and acceptability of AASP for autistic adults. A majority of autistic participants were satisfied with the AASP. Participant feedback on the AASP and research methods was positive. There was excellent retention in both arms, and a majority of all study outcome measures were completed with few missing data points. Fidelity of delivery of AASP was excellent. Overall, results suggest that a definitive RCT to determine the effectiveness of AASP is feasible and acceptable. Future research should explore the efficacy of AASP in routine clinical practice.

## Additional information

### *CRediT contribution statement*

**Jacqui Rodgers (https://orcid.org/0000-0002-1759-316X):** Conceptualisation, Data curation, Formal analysis, Funding acquisitions, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – reviewing and editing.

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**Isabel Gordon (https://orcid.org/0000-0002-3493-2215):** Data curation, Formal analysis, Project administration, Writing – original draft, Writing – reviewing and editing.

This synopsis should be referenced as follows:
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## Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Anonymised data will be made available upon reasonable request which must include a protocol and statistical analysis plan and not be in conflict with our pre-specified publication plan. Requests for data will be considered by the Chief Investigator, the independent trial steering committee and data monitoring committees.

## Ethics statement

A favourable ethical opinion was been obtained for stages 1 and 2 via IRAS (REC 20/WA/0101) on 19 May 2020. The stage 3 feasibility trial was approved by the NHS Health Research Authority and Wales Research Ethics Committee (Wales REC 5; REC Reference: 20/WA/0101; IRAS Project ID: 280742) on 12 July 2021. Any significant changes to the protocol were submitted in writing to the sponsor and Research Ethics Committee. Informed consent was obtained from all individuals by the RAs before initiation of study procedures.

## Information governance statement

Newcastle University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, Newcastle University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.ncl.ac.uk/data-protection/data-protection-policy/

## Disclosure of interests

***Full disclosure of interests:*** Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/CGDF8525.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

## *Trial registration*

This trial is registered as ISRCTN70594445.

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## *Award publications*

This synopsis provided an overview of the research award *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*. Other articles published as part of this thread are:

Rodgers J, Goodwin J, Nielsen E, Bhattarai N, Heslop P, Kharatikoopaei E, *et al*. Adapted suicide safety plans to address self-harm, suicidal ideation, and suicide behaviours in autistic adults: protocol for a pilot randomised controlled trial. *Pilot Feasibility Stud* 2023;**9**:31. https://doi.org/10.1186/s40814-023-01264-8

Rodgers J, Cassidy S, Pelton M, Goodwin J, Wagnild J, Bhattarai N, *et al*. Feasibility and acceptability of autism adapted safety plans: an external pilot randomised controlled trial. *EClinicalMedicine* 2024;**73**:102662. https://doi.org/10.1016/j.eclinm.2024.102662

Bhattarai N, Goodwin J, Pelton M, Gordon I, Rodgers J, Cassidy S, *et al*. Health economic evaluation of Autism Adapted Safety Plans: findings on feasibility of tools from a pilot randomised controlled trial. *BMC Health Serv Res* 2025;**25**:473. https://doi.org/10.1186/s12913-025-12642-8

Goodwin J, Gordon I, O'Keeffe S, Carling S, Berresford A, Bhattarai N, *et al*. Adapting Safety Plans for Autistic Adults with Involvement from the Autism Community. *Autism Adulthood* 2025;**7**:293–302. https://doi.org/10.1089/aut.2023.0124

For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR129196).

## *Additional outputs*

Nielsen E, Goodwin J. Reducing self-harm and suicide in autistic adults. (blog) Biomedcentral. Does one size fit all? Adapting Safety Planning Intervention with and for autistic adults (netecr.org). netECR. 2021.

## Talks, presentation and seminars

**2023**

Cassidy S. *Presentation to Inform Suicide Prevention for Autistic Adults in Israel.*

Cassidy S. *Presentation at the Cundill Centre about the Development and Use of Autism Adapted Safety Plans.*

Pelton M. *Presentation to Autistic People, Supporters and Clinicians about Suicide Prevention for Autistic People Organised by Autistica for World Suicide Prevention Day 2023.*

Cassidy S. *Presentation to NHS Mental Health Professional Training Workshop as Part of the Community of Practice National Autism Trainer Program.*

Goodwin J. *Presentation for Joint Meeting of NHSEI (NHS England and NHS Improvement)/NCISH (National Confidential Enquiry into Suicie and Safety in Mental Health)/MaSH (Manchester Self-Harm Project)/PSTRC (Patient Safety Translational Research Centre).*

Rodgers J. *Presentation Adapting Safety Planning Intervention with and for Autistic Adults.* International Society for Autism research (INSAR), Stockholm, May 2023.

**2022**

Rodgers J. *Presentation at the UK Suicide Prevention Leads Meeting.*

Goodwin J, Nielsen E. *Presentation to Sheffield Autism Partnership Board.*

Rodgers J. *Presentation on Autism and Mental Health to North East London NHS Foundation Trust.*

Rodgers J. *Presentation to Milton Keynes County Council.*

Rodgers J. *Presentation to The Hive.*

**2021**

Goodwin J. *Presentation at North East Suicide Prevention Network.*

Rodgers J. *Keynote Address on Mental Health in Autism, Chile.*

Rodgers J. *Presentation at Doncaster Local Authority Research Links (LARKS).*

Cassidy S. *Invited Workshop Attendance with Autism Suicide Prevention Action Group.*

Nielsen E, Goodwin J, Isard L, Newell N, O'Connor R, Townsend E, Cassidy S. *Adapting Safety Plans with and for Autistic Adults and Those Who Support Them. International Academy of Suicide Research/American Foundation for Suicide Prevention.*

**2020**

Rodgers J. *Presentation for the Neurology, Neuroscience and Neurodisability Research Theme and Newcastle University.*

Rodgers J. *Suicide and Autism – Seminar Presentation for World Mental Health Day.*

Rodgers J. *Keynote Address About Suicide and Depression in Autism at Association for Child and Adolescent Mental Health.*

### Key policy impact

**2023**

Citation of Rodgers *et al.*, 2023 in Department for Health and Social Care Suicide Prevention Strategy 2023–2028. URL: www.gov.uk/government/publications/suicide-prevention-strategy-for-england-2023-to-2028/suicide-prevention-in-england-5-year-cross-sector-strategy

### *About this synopsis*

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## List of abbreviations

| | |
|---|---|
| AASP | autism adapted safety plans |
| CSQ-8 | Client Satisfaction Questionnaire-8 |
| CV | contingent valuation |
| DBT | Dialectic Behaviour Therapy |
| DCE | discrete choice experiment |
| EQ-5D-5L | EuroQol-5 Dimensions, five-level version |
| EQ-5D-VAS | EuroQol-5 Dimensions visual analogue scale |
| LASSO | least absolute shrinkage and selection operator |
| LEAP | Lived Experience Advisory Panel |
| NIHR | National Institute for Health and Care Research |
| PPI | patient and public involvement |
| RCT | randomised controlled trail |
| SAE | serious adverse event |
| SITBI | Self-Injurious Thoughts and Behaviours Interview |
| SUS | System Usability Scale |

## References

1. Department of Health and Social Care. *Suicide Prevention in England: 5-Year Cross-Sector Strategy*. London: UK Government; 2023. URL: www.gov.uk/government/publications/suicide-prevention-strategy-for-england-2023-to-2028/suicide-prevention-in-england-5-year-cross-sector-strategy (accessed 30 November 2023).
2. Brugha TS, Spiers N, Bankart J, Cooper S, McManus S, Scott FJ, *et al*. Epidemiology of autism in adults across age groups and ability levels. *Br J Psychiatry* 2016;**209**:498–503.
3. Maenner MJ, Shaw KA, Bakian AV, Bilder DA, Durkin MS, Esler A, *et al*. Prevalence and characteristics of

autism spectrum disorder among children aged 8 years: autism and developmental disabilities monitoring network, 11 sites, United States, 2018. *MMWR Surveill Summ* 2021;**70**:1–16.

4. Cassidy S, Au-Yeung S, Robertson A, Cogger-Ward H, Richards G, Allison C, *et al*. Autism and autistic traits in those who died by suicide in England. *Br J Psychiatry* 2022;**221**:683–91.
5. Cusack J, Sterry R. *Your Questions: Shaping Future Autism Research*. London: Autistica; 2016.
6. Cassidy S, Cogger-Ward H, Robertson AE, Goodwin J, Rodgers J. *Autism Community Priorities for Suicide Prevention: An International Society for Autism Research Policy Brief*. Kansas City, MO: International Society for Autism Research; 2021. URL: https://cdn.ymaws.com/www.autism-insar.org/resource/resmgr/files/policybriefs/2021-insar_policy_brief.pdf (accessed 30 November 2023).
7. Brown CM, Newell V, Sahin E, Hedley D. Updated systematic review of suicide in autism: 2018–2024. *Curr Dev Disord Rep* 2024;**11**:225–56.
8. Huntjens A, Van Den Bosch Wies LMC, Sizoo B, Kerkhof A, Smit F, Van Der Gaag M. The effectiveness and safety of dialectical behavior therapy for suicidal ideation and behavior in autistic adults: a pragmatic randomized controlled trial. *Psychol Med* 2024;**54**:2707–18. https://doi.org/10.1017/S0033291724000825
9. Chen EY, Matthews L, Allen C, Kuo JR, Linehan MM. Dialectical behavior therapy for clients with binge-eating disorder or bulimia nervosa and borderline personality disorder. *Int J Eat Disord* 2008;**41**:505–12.
10. Green JD, Kearns JC, Rosen RC, Keane TM, Marx BP. Evaluating the effectiveness of safety plans for military veterans: do safety plans tailored to veteran characteristics decrease suicide risk? *Behav Ther* 2018;**49**:931–8.
11. Stanley B, Brown GK, Brenner LA, Galfalvy HC, Currier GW, Knox KL, *et al*. Comparison of the safety planning intervention with follow-up vs usual care of suicidal patients treated in the emergency department. *JAMA Psychiatry* 2018;**75**:894–900.
12. Schwartzman JM, Smith JR, Bettis AH. Safety planning for suicidality in autism: obstacles, potential solutions, and future directions. *Pediatrics* 2021;**148**:e2021052958.
13. Stanley B, Brown GK. Safety planning intervention: a brief intervention to mitigate suicide risk. *Cogn Behav Pract* 2012;**19**:256–64.
14. Camm-Crosbie L, Bradley L, Shaw R, Baron-Cohen S, Cassidy S. 'People like me don't get support': autistic adults' experiences of support and treatment for mental health difficulties, self-injury and suicidality. *Autism* 2019;**23**:1431–41.
15. Crane L, Adams F, Harper G, Welch J, Pellicano E. *Know Your Normal: Mental Health in Young Autistic Adults*. London: UCL Institute of Education; 2017.
16. Anderberg E, Cox JC, Neeley Tass ES, Erekson DM, Gabrielsen TP, Warren JS, *et al*. Sticking with it: psychotherapy outcomes for adults with autism spectrum disorder in a university counseling center setting. *Autism Res* 2017;**10**:2048–55.
17. Cassidy S, Bradley L, Shaw R, Baron-Cohen S. Risk markers for suicidality in autistic adults. *Mol Autism* 2018;**9**:1–14.
18. Ghaziuddin M, Ghaziuddin N, Greden J. Depression in persons with autism: implications for research and clinical care. *J Autism Dev Disord* 2002;**32**:299–306.
19. Wigham S, McConachie H. Systematic review of the properties of tools used to measure outcomes in anxiety intervention studies for children with autism spectrum disorders. *PLOS ONE* 2014;**9**:e85268.
20. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al*. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;**374**:n2061.
21. Goodwin J, Gordon I, O'Keeffe S, Carling S, Berresford A, Bhattarai N, *et al*. Adapting safety plans for autistic adults with involvement from the autism community. *Autism in Adulthood* 2025;**7**:293–302. https://doi.org/10.1089/aut.2023.0124.
22. Rodgers J, Goodwin J, Nielsen E, Bhattarai N, Heslop P, Kharatikoopaei E, *et al*. Adapted suicide safety plans to address self-harm, suicidal ideation, and suicide behaviours in autistic adults: protocol for a pilot randomised controlled trial. *Pilot Feasibility Stud* 2023;**9**:1–9.
23. Rodgers J, Cassidy S, Pelton M, Goodwin J, Nielsen E, Wagnild J, Bhattarai N, *et al*. Feasibility and acceptability of autism adapted safety plans: an external pilot randomised controlled trial. EClinicalMedicine 2025;84:103260. https://doi.org/10.1016/j.eclinm.2025.103260
24. Bhattarai N, Goodwin J, Pelton M, Gordon I, Rodgers J, Cassidy S, *et al*. Health economic evaluation of intervention aimed towards autistic people: findings on feasibility of tools from a pilot randomised controlled trial. *BMC Health Serv Res* 2025;**25**:473.
25. Milton DEM. On the ontological status of autism: the 'double empathy problem'. *Disab Soc* 2012;**27**:883–7.
26. Cassidy SA, Bradley L, Cogger-Ward H, Rodgers J. Development and Validation of the Suicidal Behaviours Questionnaire: autism spectrum conditions in a

community sample of autistic, possibly autistic and non-autistic adults. *Mol Autism* 2021;**12**:1–46.

27. Griffiths S, Allison C, Kenny R, Holt R, Smith P, Baron-Cohen S. The Vulnerability Experiences Quotient (VEQ): a study of vulnerability, mental health and life satisfaction in autistic adults. *Autism Res* 2019;**12**:1516–28.
28. Smith RD. Construction of the contingent valuation market in health care: a critical assessment. *Health Econ* 2003;**12**:609–28.
29. Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. *Br Med Bull* 2010;**96**:5–21.
30. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
31. Feng Y, Parkin D, Devlin NJ. Assessing the performance of the EQ-VAS in the NHS PROMs programme. *Qual Life Res* 2014;**23**:977–89.
32. Lancsar E, Louviere J. Conducting discrete choice experiments to inform healthcare decision making: a user's guide. *PharmacoEconomics* 2008;**26**:661–77.
33. Cassidy S, Bradley L, Bowen E, Wigham S, Rodgers J. Measurement properties of tools used to assess depression in adults with and without autism spectrum conditions: a systematic review. *Autism Res* 2018;**11**:738–54.
34. Pelton MK, Crawford H, Robertson AE, Rodgers J, Baron-Cohen S, Cassidy S. Understanding suicide risk in autistic adults: comparing the interpersonal theory of suicide in autistic and non-autistic samples. *J Autism Dev Disord* 2020;**50**:3620–37.
35. Price A, Albarqouni L, Kirkpatrick J, Clarke M, Liew SM, Roberts N, Burls A. Patient and public involvement in the design of clinical trials: an overview of systematic reviews. *J Eval Clin Pract* 2018;**24**:240–53.
36. Fletcher-Watson S, Adams J, Brook K, Charman T, Crane L, Cusack J, *et al*. Making the future together: shaping autism research through meaningful participation. *Autism* 2019;**23**:943–53.
37. Lewis SP, Hasking P. Putting the 'self' in self-injury research: inclusion of people with lived experience in the research process. *Psychiatr Serv* 2019;**70**:1058–60.
38. Slade G. *Diverse Perspectives: The Challenges for Families Affected by Autism from Black, Asian and Minority Ethnic Communities*. London: The National Autistic Society; 2014. URL: https://positiveaboutautism.co.uk/uploads/9/7/4/5/97454370/nas-diverse-perspectives-report-1.pdf (accessed 30 November 2023).
39. Dattaro L, Jeffrey-Wilensky J. *Massive U.K. Study Finds Racial and Ethnic Disparities in Autism Diagnoses*. 2021. URL: www.spectrumnews.org/news/massive-u-k-study-finds-racial-ethnic-disparities-in-autism-diagnoses/ (accessed 30 November 2023).
40. Ruehl I. *Autism Incidence in England Varies by Ethnicity, Class, Location*. 2022. URL: www.spectrumnews.org/news/autism-incidence-in-england-varies-by-ethnicity-class-location/ (accessed 30 November 2023).
41. O'Nions E, Petersen I, Buckman JEJ, Charlton R, Cooper C, Corbett A, *et al*. Autism in England: assessing underdiagnosis in a population-based cohort study of prospectively collected primary care data. *Lancet Reg Health Eur* 2023;**29**:100626.
42. Roman-Urrestarazu A, van Kessel R, Allison C, Matthews FE, Brayne C, Baron-Cohen S. Association of race/ethnicity and social disadvantage with autism prevalence in 7 million school children in England. *JAMA Pediatr* 2021;**175**:e210054.
43. Memon A, Taylor K, Mohebati LM, Sundin J, Cooper M, Scanlon T, de Visser R. Perceived barriers to accessing mental health services among black and minority ethnic (BME) communities: a qualitative study in Southeast England. *BMJ Open* 2016;**6**:e012337.
44. Diemer MC, Gerstein ED, Regester A. Autism presentation in female and Black populations: examining the roles of identity, theory, and systemic inequalities. *Autism* 2022;**26**:1931–46.

# Appendix 1

**TABLE 2** Protocol amendments

| Amendment | Details | Submitted (NIHR) | Approval (NIHR) | Submitted (ethics) | Approval (ethics) | Implemented at sites |
|---|---|---|---|---|---|---|
| Amendment 1 (Protocol V2) | (a) Introduce remote/virtual consent and assessment procedures | 7 December 2020 | 8 December 2020 | 8 December 2020 | 9 December 2020 | 9 December 2020 |
| Amendment 2 (Protocol V3) | (b) Confirm outcome measures for stage 3<br>(c) Introduce self-referral route to stage 3<br>(d) Replace Prof Kasim with Dr Ogundimu | 4 June 2021 | 5 June 2021 | 25 June 2021 | 12 July 2021 | 12 July 2021 |
| Amendment 3 (Protocol V4) | (e) Change length of stage 3 to increase recruitment period by 4 months to mitigate COVID delays<br>(f) Schedule of events table edited to correct typos and match in-text description<br>(g) Replace Dr Ensum with Dr Zahhadi as DMC Chair | 10 February 2022 | 11 February 2022 | 10 February 2022 | 11 February 2022 | 11 February 2022 |
| Amendment 5[a] (Protocol V4) | (h) Change recruitment procedures to include social media | 29 March 2022 | 30 March 2022 | 29 March 2022 | 30 March 2022 | 30 March 2022 |
| Amendment 6 (Protocol V4) | (i) 6-month no cost extension (non-notifiable amendment) | 18 August 2022 | 18 August 2022 | 18 August 2022 | 18 August 2022 | 18 August 2022 |

a No version 4 due to error in documentation. Item (h) was submitted to ethics with an outdated excel spreadsheet labelled as amendment 4. It was returned by ethics and resubmitted on the correct excel spreadsheet (no change in content to the amendment) and subsequently labelled as amendment 5.

This synopsis should be referenced as follows: Rodgers J, Bhattarai N, Goodwin J, Gordon I, Heslop P, Nielsen E, *et al.* Adapted Safety Plans to Address Self-Harm and Suicide Behaviours in Autistic Adults: single arm-feasibility trial and external pilot RCT. *Public Health Res* 2025;**13**(10). https://doi.org/10.3310/CGDF8525