Project title: Canine-assisted interventions as adjunctive treatment to improve mental health outcomes: extending methodological guidelines for robust intervention research and preparing the grounds for a definitive trial

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Plain English Summary

Why we did this research
Dog-assisted interventions (DAIs) are activities that aim to improve people's health and well-being through the presence of, or engagement with, a dog. These activities are becoming more common in health, care and educational settings, especially to help with mental health.

Spending time with a dog can help patients feel more relaxed and motivated to complete their treatment. It can also help them talk more easily with their health care professionals. This could mean patients get better quicker, which would save the NHS time and money.

Although they are being used more often, we do not have enough high-quality, scientific evidence to prove that these activities work. Many past studies were too small or missed important details. We do not fully understand who these activities help the most, or how to make them as effective as possible.

What we did
Our project aimed to improve research in this area. We wanted to create clear guidelines that can help researchers plan, carry out and report their work better. To do this we:

- Looked at completed studies to understand the main challenges, and find out who is most likely to benefit from these activities.
- Ran surveys and spoke to experts to find out the most important things to consider.

What we found
This process helped us understand where DAIs are already happening, what works well, and where there are gaps in our knowledge.

We created two new checklists for researchers. These checklists will help them plan their research and share their results clearly. We also created a guidance document with examples of how these checklists should be used.

What happens next
We hope our findings will change the way these activities are run, making them safer and more helpful. We will apply for funding so we can test these new checklists.

Description of Research

Background

Animal-assisted interventions are increasingly used in healthcare, education and social services to improve mental health outcomes for populations across the life span. Dogs are the most commonly involved species, perhaps due to their emotional connection with humans and their ability to respond to human cues and training (1, 2). Dog-assisted interventions (DAIs) include a) structured, goal-oriented dog-assisted therapy delivered by trained professionals and b) unstructured, spontaneous dog-assisted activities delivered by volunteers (3).

The presence of or engagement with a dog has been shown to have the capacity to benefit therapeutic interventions in multiple ways. For example, DAIs have the capacity to catalyse the building of a rapport between patient and therapist, improving therapeutic alliance (4-7), and patient engagement (8-10). This can lead to greater motivation and increased adherence to treatment (11) and potentially better and faster treatment outcomes (12, 13). However, a stronger evidence base of more rigorous research is needed to help understand how to maximise potential benefits and minimise challenges and risks.

Randomised controlled trials (RCTs) are the gold standard for evaluating healthcare innovations. RCTs evaluating DAIs present unique design challenges due to their complex nature, i.e. the involvement of multiple parties such as the dog, dog handler and service users (14, 15), and the complexity of interspecies interactions. Although DAI intervention research has been expanding (16-21), it commonly suffers from multiple methodological issues such as lack of statistical power, absence of standardised intervention protocols, and poorly designed control conditions (9, 14, 22). Poor reporting further complicates reproducibility and comparability (22, 23). To address design and reporting issues in RCTs, the CONSORT and SPIRIT guidelines were developed, with recent revisions in 2025 (24, 25).

This programme developed DAI-specific extensions of the CONSORT 2025 and SPIRIT 2025 checklists, aiming to improve reporting standards in this field. These outputs are crucial for improving the design, conduct, and reporting of DAI RCTs, and can help pave the way to a more robust evidence-base, higher safety standards for all parties involved and more effective interventions benefiting the wider public. We intend to use these outputs to design, conduct, and report a high-quality pragmatic RCT to determine the clinical and cost-effectiveness of a DAI intervention in a mental health priority area.

Our specific objectives were to:

<u>1. Develop DAI extensions to the SPIRIT and CONSORT statements:</u>

- Identify common shortcomings in DAI RCT design and reporting through a systematic review to develop a long list of extension concepts/items,
- Identify stakeholder perspectives to finalise the list of extensions,
- Gain consensus on a short-list of extension concepts/items.

<u>2. Finalise and disseminate DAI-specific guidelines and recommendations:</u>

- Hold a consensus meeting to agree final extension items,
- Finalise items and develop an explanation and elaboration (E&E) document,

- Disseminate extensions and E&E widely.

3. Identify a priority mental health population for future DAI research:
- Conduct a systematic review to evaluate effectiveness of DAIs in mental health and neurodevelopmental conditions,
- Survey and map existing DAI provision for mental health populations through a national survey of DAI providers,
- Create a short-list of interventions and settings/populations with stakeholders to identify the target setting/population for future research.

4. Preliminary health economic (HE) work:
- Systematically review the literature for HE information in the field;
- Develop a HE data collection plan.

Cross-cutting theme: Extend and further develop networking and public and patient involvement (PPI) capacity in DAI research:
- Develop a 'Community of Interest' with key representatives,
- Engage stakeholders in identifying key reporting considerations, developing and disseminating the final extensions, and identifying the target population,
- Assemble a population-specific PPI and expert advisory group to support future research development

Methods

The development of the SPIRIT and CONSORT DAI extensions followed a structured, multi-phase approach:

Phase 1. Systematic Review: The first phase involved conducting a systematic review of the literature to identify methodological shortcomings of DAI RCTs. This review further aimed to identify key reporting considerations and develop a comprehensive 'long-list' of SPIRIT and CONSORT extension items. Additionally, the review assessed the effectiveness of DAIs for populations with mental health and neurodevelopmental conditions, as the first stage in the process of identifying the top priority mental health/neurodevelopmental population for the future RCT. The systematic review was registered on (CRD42024526375).

Phase 2. Delphi Survey: In the second phase, a three-round Delphi survey (26) was conducted to refine the long list of items. Participants included international experts in DAI and methodological research, and DAI providers. The Delphi process allowed participants to rate the importance of each concept using a 9-point Likert scale and propose new items for inclusion. Items were categorised as follows:
- **Consensus in:** ≥70% of participants scored 7–9, and <15% scored 1–3.
- **Consensus out:** ≥70% of participants scored 1–3, and <15% scored 7–9.
- **No consensus:** Any other outcome.

Phase 3. Consensus Workshops: The third phase involved two online consensus workshops. Experts in DAI and methodology research were invited to review items that had not reached consensus, finalise the wording of items which had reached consensus, and suggest appropriate examples from the literature, with references, for the E&E document

that accompanies our DAI-extension checklists. Key discussions were documented, and iterative revisions were made based on workshop feedback.

Upon publication of the updated SPIRIT 2025 and CONSORT 2025 guidelines, all newly developed extensions were mapped against these new versions to ensure relevance and applicability. Content was reviewed and agreed upon by the wider study advisory group.

National Survey of DAI Providers: A bespoke survey instrument was developed with stakeholder input to collect data relevant to understanding DAI service provision in the UK. The survey was piloted by our PPI and expert advisory panels. Prospective participants were invited to follow a link to the survey on Qualtrics, where they were presented with a Participant Information Sheet and consent form. Following consent participants completed questions that covered the following areas: demographic data, organisational data, confidence and barriers, health and safety, dog characteristics, dog welfare, dog selection and training.

Preparatory HE work: the systematic review followed the PRISMA 2020 guidelines. Searches were conducted in MEDLINE, EMBASE, PsycINFO, EconLit, CINAHL Ultimate, Cochrane Library, and Web of Science databases up to February 2025. Studies were selected based on the PICOS framework, including DAIs as an intervention and reporting cost-related or economic evaluation outcomes. Data extraction was conducted using a structured template, and study quality was planned to be assessed using the CHEERS checklist.

Network building and PPI capacity development: We identified DAI providers, academics, third sector organisations, staff involved in supporting primary school children with special needs and parents interested in supporting research related to neurodiversity and DAIs using existing clinical and academic and co-production networks and social media advertising. Involvement was targeted towards contribution to the DELPHI study for the SPIRIT and CONSORT guidelines, discussions related to priorities for future research, and at the end of this PDG, input towards planning our PGfAR application.

Changes from Original Plan: The original plan outlined the development of SPIRIT and CONSORT extensions based on the 2013 and 2010 guidelines, respectively. However, upon release of the updated SPIRIT 2025 and CONSORT 2025 guidelines in the summer 2025, we mapped all of our extensions against these new versions to maximise relevance and applicability. This adjustment did not affect the content but enhanced alignment with current standards and is a notable achievement, given the particular timing involved.

Research Findings

Phase 1. Systematic Review The systematic review identified 33 RCTs evaluating DAIs. The mean adherence to the CONSORT statement was 48.6%. Data extracted during this phase produced 85 reporting recommendations, 44 SPIRIT items and 41 CONSORT items. Reporting recommendations applicable to both SPIRIT and CONSORT statements were identified.

Findings on effectiveness of DAIs were mixed. Of the studies assessing social skills and/or behaviour, 8 out of 14 (57%) reported positive effects. Similarly, 6 of 14 studies (43%)

evaluating outcomes related to depression demonstrated beneficial impacts. Only two of six studies (33%) assessing agitation reported reductions. These results suggest that DAIs may hold particular promise in improving social skills and behaviours across various population groups, and that further robust research is needed to fully understand impact across a variety of populations and contexts.

Phase 2. Delphi Survey: 85 reporting recommendations (SPIRIT, n= 44 items, and CONSORT, n= 41 items) were included in the Delphi survey, which ran from April to September 2024. The survey had 83, 74, and 71 participants completing rounds one, two, and three respectively. The majority of participants were researchers/academics (70%), followed by therapists/counsellors/clinicians (18%). Participants had an average of 11 years of experience in the field of animal-assisted interventions and had published an average of 7 papers in this field.

Round One: From the 85 items presented for rating:

- Consensus in: 64 items (75%) (SPIRIT, n= 34 and CONSORT, n= 30),
- Consensus out: 0 items,
- No consensus: 21 items (25%) (SPIRIT, n= 10 and CONSORT, n= 11).

Thirteen new items were suggested, six of which were added to round two after review.

Round Two: From the 91 items presented for rating:

- Consensus in: 80 items (88%) (SPIRIT, n= 45 and CONSORT, n= 35)
- Consensus out: 0 items
- No consensus: 11 items (12%) (SPIRIT, n= 3 and CONSORT, n= 8).

New items included in this round were presented in round three regardless of consensus status.

Round Three: From the 16 items presented for rating:

- Consensus in: 14 items (88%) (SPIRIT, n= 6 and CONSORT, n= 8)
- Consensus out: 0 items
- No consensus: 2 items (13%) (SPIRIT, n= 1 and CONSORT, n= 1).

Phase 3.

3.1. Consensus Workshops: The consensus workshops were attended by seven experts in DAI research and methodology research, along with three members of the core study team. The wording for each item at consensus was reviewed and refined. The two items that had not reached consensus in the Delphi survey were discussed and agreement was reached to include them in the final checklists following minor changes in wording.

Checklist Finalisation: The checklists agreed upon in the consensus workshops were iteratively reviewed by the core study team, and elaboration text was drafted. Examples of good reporting were sourced by the study team and consensus workshop members. During the process of mapping the drafted DAI extensions to the updated SPIRIT and CONSORT 2025 checklists, an item previously presented only in the SPIRIT DAI checklist was added to the CONSORT DAI checklist due to the addition of CONSORT 12b.

The final checklists and E&E document were pilot tested by four authors, three experienced in DAI research and one without prior experience. A total of 71 DAI extensions

were created, SPIRIT, n= 36 and CONSORT, n= 35. All items were designed to extend rather than replace the original SPIRIT 2025 or CONSORT 2025 items.

3.2. National survey of DAI providers: Of 72 invitations sent to DAI organisations and therapists identified through extensive internet research and consultation with our PPI members of providers, 31 participants completed the survey (response rate: 41.3%).

DAI settings and target populations: Most participants (80.6%) reported delivering DAIs in non-NHS settings, including private mental health services (n = 14), care homes (n = 9), and hospices (n = 5). DAIs were also provided in educational settings (41.9%), mainly schools (n = 12) and universities (n = 7), NHS mental health services (32.3%), and NHS physical health services (29.0%). Within NHS settings, DAIs were used across adult, older adult, Child and Adolescent Mental Health Services (CAMHS), forensic, inpatient, intensive care unit (ICU), outpatient, and GP services. Two-thirds (67.7%) or respondents were able to report how many institutions their affiliated organisation served with DAIs, with estimates totalling 7,679. Populations included adults and young people with mental, neurodevelopmental, physical, or neurodegenerative conditions.

DAI types, frequency, duration and session structure: Most participants reported delivering dog-assisted therapy (61.3%) and dog-assisted activities (51.6%). Only 22.6% said sessions always had clear goals, while 38.7% were unsure. DAIs were mainly delivered individually (90.3%), with some group sessions involving peers (61.6%) or relatives (19.4%). Session duration often varied (58.1%), though 22.6% typically ran for 6–10 weeks. Frequency also varied (29.0%), but most commonly sessions occurred weekly (45.2%) or multiple times per week (22.6%). Session length was usually 31–60 minutes (54.8%), with some lasting under 30 minutes (16.1%) or up to two hours (29.0%).

Dog-handler team training: Only just over half of participants (54.8%) reported that dog handlers providing the DAIs received training, primarily in dog wellbeing and safety (94.1%), risk assessment (94.1%), service user safety (88.2%), and dog body language (88.2%). Dogs reportedly also underwent training [ER1], most commonly in basic obedience (80.6%), handling (77.4%), greeting (74.2%), socialisation in work-like environments (74.2%), and to support building the human-dog bond (67.7%).

Dog characteristics, selection and welfare: Dog breeds in DAI sessions most commonly represented the Gundog group (48.4%) and crossbreeds (48.4%), followed by Working (29.0%) and Toy (25.8%) groups. Starting age varied, with most dogs beginning work at 7–12 months (41.9%). Maximum working age ranged, with 32.3% setting it at 10 years, while 25.8% had no upper limit. All participants reported using temperament/behaviour as a selection criterion; others included health checks (45.2%), obedience tests (32.3%), and physical traits (19.4%). Most (83.9%) reported routine health checks. Dog wellbeing was reported to be monitored through handler observation (90.3%), access to water (87.1%), and retreat space (74.2%). Most organisations (80.7%) reported having formal processes for reporting incidents or undesirable behaviour.

Barriers and facilitators to DAI provision: While 19.4% reported no barriers to DAI implementation, common challenges included limited delivery spaces (35.5%), infection control concerns (32.3%), and difficulty matching dogs to service users (22.6%). Other

issues involved dog welfare monitoring and interprofessional collaboration. Reported facilitators included well-trained dog-handler teams, ethical animal welfare practices, careful dog-user matching, time for relationship building, and ongoing evaluation.

3.3. Shortlist of setting/population combinations for future research

Based on findings from our systematic review and national survey, we identified the improvement of social skills and behaviours as a particularly promising target. Adding results from our survey, which reported most frequent DAI provision for neurodevelopmental and mental health goals, and in view of recently published policy reports on support gaps (The Children's Commissioner, October 2024), we identified children with neurodevelopmental conditions as potential study population, and schools as target setting. We presented this suggestion to our network and stakeholders and arranged early engagement sessions with school staff (head teachers, Special Educational Needs Coordinators, teachers) and DAI providers, where it was met with support and enthusiasm, especially as it offers opportunities to reduce burden on the NHS. Engagement in the context of preparing our planned PGfAR application continues.

4. Preparatory HE work

Of 1,323 records identified, only five studies met the inclusion criteria. No comprehensive economic evaluations of DAI were found, and the available cost data were limited, incomplete, or outdated. Our scoping review summarises the key factors influencing the cost-effectiveness of DAIs, including the costs associated with therapy dogs, staff costs for intervention delivery, and additional operational costs, as well as potential health benefits and cost savings, which collectively determine the overall cost-effectiveness of DAIs. We have drafted a basic instrument to collate costs relevant to our planned PGfAR application intervention; however, this will need to be refined if and when the development work for the intervention progresses.

Conclusions

The development of the **SPIRIT and CONSORT** 2025 DAI extensions represent a major advancement in improving the quality and consistency of DAI research. These reporting guidelines include 71 DAI-specific items (n= 36 for SPIRIT, n= 35 for CONSORT). They provide the minimum essential requirements for designing and reporting DAI clinical trials, ensuring that critical aspects of DAI research are consistently and transparently reported. This is expected to improve the quality and scientific rigour of DAI research.

The national **survey** of DAI provision highlighted the breadth and versatility of DAIs across health and care settings in the UK, benefitting people of all ages and backgrounds, and being especially used for neurodevelopmental and mental health purposes. The survey revealed that significant variability in practices remains. In particular, practitioner training and animal welfare procedures require greater standardisation and validation to ensure DAIs are delivered safely and ethically, and to support consistent outcomes and scalability.

There is a substantial gap in **economic evidence** regarding DAIs. Future research should focus on standardised cost-reporting frameworks and high-quality economic evaluations to support informed decision-making and broader implementation in healthcare settings. Prospective clinical trials with integrated cost-effectiveness analyses are highly

recommended to establish their economic viability and long-term impact.

The need for **PPI** in future research in this area is recognised. Including PPI will help ensure future research can be accessible and meaningful for stakeholders. This includes both the development of intervention content and delivery aspects, and aspects relating to research procedures, including data collection via standard validated instruments that can sometimes be difficult to engage with for under-represented populations.

Improving the quality and consistency of DAI research has **important implications for health and social care, and education**. A stronger evidence-base will increase confidence in the safety, effectiveness, and ethical delivery of DAIs, encouraging wider adoption across services. High-quality research will enable more tailored DAIs based on population needs, improve training standards for practitioners and handlers, and inform national policy and funding decisions. This could support the integration of DAIs into mainstream care and educational settings, especially to provide adjunctive support to mental health and wellbeing provision. Standardised approaches will also help reduce regional inequalities in access and ensure that both service users and therapy animals are protected. More rigorous research will enable DAIs to deliver more consistent, meaningful benefits across a range of settings and support their long-term sustainability as a complementary intervention.

Patient and Public Involvement

Aim

The aim of PPI, including the expert panel, in this programme was to ensure that the design, development, and dissemination of methodological guidelines for dog-assisted intervention (DAI) research in mental health and neurodevelopmental conditions were grounded in real-world experience. PPI input was integral to shaping the outputs for future clinical research use and identifying relevant populations, and settings for future randomised controlled trial (RCT) delivery. It continues to be central to the development of our future plans for research.

Methods

Early phase: A PPI and expert advisory panel were established at the start of the project, consisting of 22 members, including DAI charity representatives, practitioners, and DAI researchers. Members contributed iteratively to study design and delivery as the DELPHI survey evolved over three rounds, and they will continue to contribute to dissemination of findings and the design of the future RCT.

Engagement methods included:

- Quarterly newsletters to keep the panel updated, sustain engagement, and invite input on specific tasks, such as survey content and participant recruitment.
- One-to-one consultations rotating PPI members to reduce burden on all and seek input based on individual expertise.
- Workshops with DAI providers and partner meetings (e.g., with teachers using therapy dogs or National Association for Special Educational Needs (NASEN)) to identify trial delivery barriers and facilitators in educational settings.

These activities ensured a wide range of stakeholder perspectives informed the development of the SPIRIT and CONSORT DAI extensions and the identification of a target population for a future programme of study.

Late phase: Following our no-cost extension granted in April 2025, we used the additional 3 months (up to August 2025) to engage with PPI work and strengthen our PGfAR application. This involved meetings with three DAI provider specialists for schools, two special educational needs (SEN) staff, one representative of the (NASEN, one representative of the National School Dog Alliance (NSDA), one head teacher, and one children and young people's research network leader. All have expressed great enthusiasm for the planned PGfAR application and will actively support development of further PPI capacity in this specific space. We have also reached out to a panel of research-interested parents of neurodivergent children and young people to elicit interest in involvement in developing future research.

Study Results

PPI contributions to the study outputs included:

Refining the DAI-specific SPIRIT and CONSORT checklist items to ensure relevance, clarity,

and practicality of use.

Reviewing and improving, with their input, recruitment materials and strategy, leading to wider survey dissemination and a more diverse dataset.

Supporting knowledge mobilisation by sharing recruitment calls and disseminating findings through their networks.

Providing detailed insights into how educational settings operate, identifying barriers and facilitators we may encounter in DAI delivery. This has directly informed our PGfAR proposal and will help ensure its feasibility and successful delivery.

Discussion and Conclusions

PPI was embedded across all four work packages and contributed substantially to the delivery of project objectives. It improved methodological quality, expanded reach, and increased the contextual appropriateness of project outputs — including the checklist items and identification of DAI research gaps in mental health and neurodevelopmental populations. Our flexible approach ensured sustainability and minimised burden on individual members.

While a significant number of engagement activities were asynchronous (e.g., through email and newsletters), this format enabled broader participation across geographical areas and disciplines. Ms Selina Gibsone (Dogs for Good, Co-applicant) played a key role in supporting PPI recruitment from the beginning of the trial while also contributing her input, for instance, through reviewing study materials. Her contributions in facilitation PPI recruitment for the programme demonstrate how early and ongoing engagement with key partners (charity representatives) can promote PPI participation.

Reflective / Critical Perspective

A key success was the flexibility of our PPI model, which allowed for sustained input and reduced burden. Regular updates through newsletters and other electronic communications helped maintain visibility and engagement. While our contributors brought deep expertise, further direct involvement from mental health service users will strengthen future work, particularly as we move toward trial co-design.

Another learning point was the need for more synchronous engagement opportunities earlier in the project. Future PPI coordination will include more frequent virtual round tables to support real-time collaboration, particularly where plurality of voices is crucial to make informed decisions. Engagement with relevant stakeholders from schools and DAI practice is ongoing for the PGfAR application.

In sum, PPI in AD ASTRA was well-integrated, highly valued, and crucial in ensuring that research tools/outputs developed are not only methodologically sound but also meaningful and easy to use in real-world contexts.

Data Sharing

We are committed to maximising the value and utility of the outputs generated through this programme. Two key outputs will be made openly accessible to support further research, reduce duplication of effort, and accelerate the development of robust DAI research.

1. SPIRIT and CONSORT DAI extension checklists and E&E document:

Upon publication of the relevant paper these guidelines will be freely available for download via the EQUATOR Network website and the Open Science Framework (OSF). These outputs will also be openly discoverable through the article DOI. The checklist items and E&E document will be accessible to any researcher, clinician, trialist or DAI provider planning or reporting DAI research.

2. Database of DAI providers in the UK:

Following publication of relevant findings, the anonymised database (excluding personal contact details, unless publicly available or permission has been granted) will be made available to any academics, policy makers, and service providers upon request. Access will be granted via a short data access form, in line with University of York processes, to ensure appropriate and ethical use.

Both the checklists and database are expected to be made available by the end of 2025.

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