STUDY PROTOCOL

Animal assisted activities in the children’s hospital: protocol for a scoping review [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract
The introduction of animal interventions in healthcare are relatively common; however, their actual effectiveness and longer term findings are not so well known or published, especially in relation to the children's hospital setting. It is important to plot where and why animal interventions take place but also to focus on how the human animal bond impacts on children, their parents and staff in a children's hospital setting. Family members, including companion animals, are important supports which help children to relax and give them a sense of familiarity to navigate the busy and stressful hospital environment. The scoping review of the literature proposed will explore the scientific evidence for animal assisted activities (AAA) in children's hospitals and will map results prior to undertaking a full scale research project. Arksey and O'Malley's framework guided by the Joanna Briggs Institute will frame this review protocol. Appendices are used to ensure transparency of methods. The protocol is presented in narrative style to demonstrate flow and fluency and appeal to wider readership.

Keywords
animal assisted activities, pet therapy, paediatrics, children's hospital, scoping review protocol
Background

Children and young people hospitalised for surgery or medical treatment can find the experience as a most distressing event in their lives if not managed appropriately by healthcare professionals and their families (Bjork et al., 2005; Coyne, 2006; Darbyshire, 1994; Gariépy & Howe, 2003; Gibson, et al., 2010). Traditionally anxiety was managed largely through pharmacological treatments resulting in negative consequences in terms of side effects of medications and ongoing costs or demands on the health care service. Non-pharmacological interventions including play and distraction therapies have positive effects on a child’s recovery and general management of care in hospital (Al-Yateem et al., 2016; Gariépy & Howe, 2003). Gibson et al. (2010) identified that all child participants in their study reported some dislike of the hospital environment. Young children in hospital requested toys from home and older children found some comfort in photographs of pets as well as soft furnishings including their own pillows and bed covers helped in improving the hospital environment to be more homely (Gariépy & Howe, 2003; Gibson, et al., 2010; Lambert, et al., 2014). Coyne’s qualitative study; of 11 children aged seven to 14 years, located in four paediatric units in Great Britain; reported children missing aspects of their home life specifically, “Miss my mum; my dog, my sister; the atmosphere, my own bed” (Coyne, 2006 pp. 329). Family members, including family pets, are important supports which help children to relax and give them a sense of familiarity to navigate the busy and stressful hospital environment.

The hospital environment while daunting and sometimes considered ‘a scary place’ for children, it is also a busy and stressful place for the children’s parents, siblings and healthcare staff working each day in what is considered an under resourced environment (Bjork et al., 2005; Bridgeman et al., 2018; Gibson et al., 2010). Families often experience chaos and extreme loneliness throughout episodes of hospitalisation and their lives are broken, similar to, “an earthenware pot dropped and broken into pieces” (Bjork et al., 2005 pp. 270). The outcome of Gariépy & Howe’s (2003) mixed methods research study comparing children attending a hospital based treatment clinic and a healthy cohort of children in a crèche found that children need to be provided with facilitated time to access toys and activities on a regular basis to help them process their anxiety and stress caused by their illness, treatment and ongoing health concerns. Gariépy & Howe (2003) suggested future research involving observation and controlled intervention would be of benefit, particularly on an individual basis, so that the child could develop a trusting relationship with the researcher and work through which intervention best suits their needs according to their age and stage of development.

Consideration should be given to other interventions such as innovative non-pharmacological interventions or complementary therapies which include animal assisted interventions (AAIs). In AAIs, the animals themselves are the health intervention. An initial search of the literature showed that AAIs enhance positive feelings in people, raise oxytocin levels, promote improved mood and foster trusting relationships (Fine, 2015).

A recent protocol and meta-analysis by May et al. (2020) aimed to quantify the impact of brief canine therapy within the discipline of psychology. Significant positive impact of animal assisted therapy (AAT) on subjective anxiety of hospitalised children was reported by May et al. (2020). While this systematic review and meta-analysis was undertaken within the paediatric context it focused primarily on the psychological and physiological responses of children, reporting the impact of canine therapy on outcomes associated with pain and anxiety. Studies in the review were limited to randomised controlled designs (May et al. 2020). Further investment into the scientific literature of this safe, novel and efficient AAT was recommended by May et al. (2020). The proposed scoping review is broader in its approach and will include all study designs and all types of animal interventions, not only canine therapy.

A preliminary search of the international literature completed in early 2020 revealed the following studies. Vagnoli et al. (2015) investigated the effectiveness of AAI as a distraction for reducing Italian children’s pain and distress during and after phlebotomy. Significant differences were found between the intervention and control group i.e. serum cortisol levels were significantly lower denoting less stress/anxiety. Limitations in this trial included the small sample size of each group and children who participated were aged 4 to 11 years and were not previous dog owners. In future research, consideration could be given to child participants choosing whether or not they want to participate and indeed in the selection of an appropriate comparison intervention based on child participatory research methods.

Calcatera et al. (2015) explored the post-operative benefits of AAT on children’s stress and pain in the acute children’s hospital setting in Germany. Data collection involved recording of baseline parameters, salivary cortisol levels, electroencephalogram and an assessment of pain. No significant difference were reported in cortisol levels and the authors recommended alternative hormone level measures be considered in future studies. Future studies should consider more comprehensive monitoring of hormone levels as well as cortisol levels and recruit a larger sample.

America is home to a Large Pet Therapy Farm in New York City. A key piece of literature from America by Hinic et al. (2019) evaluated the effect of a brief pet therapy visit and an active comparison intervention (jigsaw puzzle) on anxiety in hospitalised children. Findings support the AAI in reducing anxiety for children and their parents. Again a small study but with a comparison intervention. More rigorous studies of psychological and physiological outcomes both in the immediate and long-term phases advised. The value of exploring more qualitative elements over a longer timeframe may also be worthy of study.

Closer to home, the Royal College of Nursing (RCN) in Great Britain (GB) have published guidance for Health Care settings introducing therapy dogs (RCN, 2018). An evaluation of an
animal-assisted intervention service established in 2012 in one children’s hospital from GB demonstrated extremely positive results. The author recommended that the initiative should be repeated in other hospitals (Uglow, 2019).

At home in Ireland, anecdotal evidence points to pet therapy taking place in hospices, nursing homes, general hospital Intensive Care Units (ICUs) and one children’s hospital. Peata, one of the Irish charities, has a pet visitation programme in place to many healthcare settings which are currently stalled due to coronavirus disease 2019 (COVID-19) (Peata, 2020).

Protocol
There are interesting themes emerging from the literature which will require further exploration such as the need for more research studies which are well planned and follow a more definitive protocol. A scoping review would enable a deeper exploration of the scientific literature on how AAI might contribute to the child’s wellbeing during and after hospitalisation. Any theories about the human-animal bond which the researchers might discuss in their articles can be mapped alongside other contextual data such as geographical location and types of animal interventions. The six stages in the Scoping Review Framework introduced by Arksey & O’Malley (2005) will help guide the review protocol and subsequent scoping review.

Aims/objectives
The aims of the systematic scoping review of the literature are:

1) To determine the extent and nature of existing literature on AAI in children’s hospitals, so that the literature can be examined and mapped.

2) To summarise and map the available evidence on AAI since its conception and to determine where and when the research was carried out specifically in relation to AAI in the children’s hospital.

3) To identify any gaps in the literature or designs worthy of further consideration and focus for future research.

Stage 1. Identification of the Scoping Review Research Question
The population, concept and context (PCCo) framework was utilised to help form the research question for this scoping review which is supported by Anderson et al. (2008) and the Joanna Briggs Institute (Peters et al., 2017; Peters et al., 2020):

“What is the scientific evidence base for animal assisted intervention (C) with children and young people (P) in the children’s hospital (Co) setting?”

The population (P) is children and young people, the concept (C) is animal assisted intervention and the context (Co) being the children’s hospital.

Stage 2. Identifying relevant studies
For a systematic review, it is important that as many relevant studies are sourced, rather than all studies (Craven & Levay, 2019). The review question has been developed using the PCCo framework, so that the search terms can closely match the themes within the literature, to retrieve focused relevant studies, rather than all studies on the topic. Including all literature from date of conception on the topic of AAI in children’s hospitals will reduce the risk of bias (Craven & Levay, 2019).

Since this review will be a systematic scoping review no restrictions on date will be made since the purpose of the review is to map the literature from its source to the current time.

Inclusion and exclusion criteria
No exclusion for language will be applied in the initial search, since it will be important to map the sources and origins of the literature, to reveal any gaps in the evidence internationally. English published studies tend to be biased towards positive findings compared to non-English-language studies where results may contain null or negative findings according to Boland et al. (2017). The research team will aim to translate the titles and abstracts of non-English studies so that they may be included in the initial screening process. It may not be possible to proceed with a translation of the entire article if it passes the inclusion criteria for the next stage of analysis. However, all results will be charted regardless of language and if funding is available and the article is considered to be a valuable addition to the review then translation may be possible.

Initially it was envisaged that the search terms entered, regarding context, would need to be restricted to the acute children’s hospital setting. This exclusion was considered necessary to ensure the focus of the review question is answered and limit the retrieval of irrelevant information outside of the acute children’s hospital setting. However, following an initial search of two to three databases there was a paucity of results and the search term for context was then expanded to ‘hospital’ rather than ‘acute children’s hospital.’ A broad search for data is consistent with scoping reviews (Arksey & O’Malley, 2005; Peters et al., 2017).

Types of studies
No limits will be applied within the initial search for types of studies. It is necessary to ensure a broad search initially including all data including reviews so that it can be mapped, and any gaps identified (Tricco et al., 2016). Qualitative, quantitative and mixed method scientific data will be of most interest. Unpublished, in-press, dissertation and website data will also be of interest to ensure a comprehensive and focused search is carried out and mapped.

Types of populations
Children and young people in the children’s hospital setting is the focus of this review and therefore the adult population will be omitted from the search terms. AAI has been researched in other populations so it will not be necessary to include them in this review. The rationale for this exclusion is important so that information can be retrieved within the focus of the review question which is AAI in children’s hospitals. The definition of a child is a person below the age of 18 years old which is adapted from the World Health Organisation...
(WHO, 2014) and United Nations. Animal Assisted Activities may not be appropriate for infants or children with an aversion to animals, however all instances of AAA will be mapped from the search results. No restriction on the type of animal intervention will be installed if it meets the population criteria of being carried out in a children’s hospital.

Types of interventions or exposure
The search string for the concept relating to animal assisted interventions will also include sibling terms such as; animal assisted activity (AAA), animal assisted therapy (AAT), animal assisted coaching (AAC) and animal assisted play therapy (AAPT). Keywords and search strings for each concept and their associated terms are listed in Table 1. The MeSH thesaurus tool within Pubmed will be utilised and thesaurus results shared across each database search to maximise search results as advocated by Sampson et al. (2009). Literature citing all types of animals will be included in the initial screening of results so that the type of animal involved in the interventions can be charted, coded and cross checked throughout the entire data set for comprehensive reporting of results.

Setting / context
It is important to search broadly yet comprehensively for literature pertaining to AAI in the children’s hospital setting as it is the phenomenon of interest to the author’s work. However, it is likely that other settings and contexts will be found following the initial search to ensure comprehensive search results are obtained. Irrelevant citations will be excluded by reviewers following further screening and in accordance with exclusion criteria.

Search strategy
In order to produce a comprehensive map for the scoping review of AAA in children’s hospitals the following databases will be searched:

**Health databases:** PubMed, CINAHL, Plus and the Cochrane Library.

**Social Sciences databases:** PsycINFO, Applied Social Sciences Index and Abstracts (ASSIA) and the Social Sciences Citation Index.

**Veterinary Medicine:** CABI VetMed Resource, Google Scholar and Ingenta Connect

**Grey Literature:** LENUS, OpenGrey, Grey Literature Report, ProQuest Dissertations and Theses, websites of the charitable organisations involving therapy animals for example: The Society of Companion Animal Studies (SCAS).

The need to search more than one bibliographic database is justified since the research question crosses more than one discipline and a broad search of the literature is required for the review (Boland et al., 2017). The databases of LENUS and OpenGrey will be searched for any grey literature meeting the search criteria. Paez (2017) asserts the important contribution grey literature can make to a review. A range of search techniques will also be utilised to reveal important grey literature such as unpublished case studies or guidelines on AAI in children’s hospitals and websites.

The keywords; animal assisted therapy; child, hospitalised; adolescent; paediatrics and hospitals, paediatric; will be entered into the search field individually then combined for each of the database searches having been carefully selected from the review question. Keywords and search strings for each concept and their associated terms are listed in Table 1.

The Joanna Briggs Institute advocates the invaluable skills of a research librarian for refining search terms and utilising tools to their maximum capacity (Peters et al., 2017 &

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### Table 1. Keywords for each search string.

| **1. Population (P):** | child or child, pre-school, minors, children or adult children or children, adult or young person or young people or paediatric or paediatrics or pediatric or pediatrics or toddler or pre-schooler or “adolescent” [Mesh] = adolescents or adolescence or teens or teen or teenagers or teenager or youth or youths or adolescents, female or adolescent, female or female adolescent or female adolescents or adolescents, male or adolescent, male, or male adolescent or male adolescents |
| **2. Concept (C):** | animal assisted interventions or interventions, animal assisted or animal assisted activity or animal assisted activities or activity, animal assisted or activities, animal assisted or animal assisted coaching or coaching, animal assisted or animal assisted play therapy or play therapy, animal assisted or “animal assisted therapy” [Mesh] = animal assisted therapies or assisted therapies, animal or assisted therapy, animal or therapies, animal assisted or therapy, animal assisted or animal facilitated therapy or animal facilitated therapies or facilitated therapies, animal or facilitated therapy, animal or therapies, animal facilitated or therapy, animal facilitated or pet therapy or pet therapies or therapies, pet therapy, pet or pet facilitated therapy or facilitated therapies, pet or facilitated therapy, pet or pet facilitated therapies or therapies, pet facilitated or therapy, pet facilitated |
| **3. Context (Co):** | children* hospital or hospital, children* or “child, hospitalised” [Mesh] = children, hospitalized or hospitalized children or hospitalized child or child, hospitalised or children, hospitalised or hospitalised children or hospitalised child or “hospitals, pediatric” [Mesh] = pediatric hospitals or hospital, pediatric or pediatric hospital or hospitals, paediatric or paediatric hospitals or hospital, paediatric or paediatric hospital or hospital ward, or children's ward or paediatric ward or pediatric ward or children's unit or paediatric unit or pediatric unit or children's clinic or paediatric clinic or pediatric clinic |

Results from 1. and 2. will be combined and then further combined with 3. to reveal full list of articles to be initially screened by title and abstract.
The author has access to a librarian (DS) with expert experience in carrying out searches using thesaurus tools and will provide assistance and support to the researcher carrying out the database searches. The highly sensitive search strategy using boolean operators, both free-text and subject headings (including MeSH when available) for each database search will be reported to ensure transparency through a clear audit trail.

Booth (2008) asserts the importance of reviewers utilising a range of techniques from their ‘toolbox.’ More traditional methods such as citation searching, contacting authors and web searching will also be employed to enhance efforts to produce a comprehensive review of published and unpublished information. Hand searching for journals, conference abstracts and hospital guidelines which may reveal additional information, because not all reports are indexed correctly and could be missed without searching manually. Citations from articles included in the full text review stage will also be obtained if not already included in the initial search results.

Stage 3. Study selection

Each search will be saved and imported into a file on Endnote X9 where results can be de-duplicated and ready for initial screening of the title and abstract by the review team. The advantage of Endnote is that a research diary of each search can be made by dating each file upon import of search results and the number of articles retrieved can then be added to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart advocated by the Joanna Briggs Institute (Peters et al., 2017 & Peters et al., 2020). A PRISMA flowchart will be produced following the completed searches which will enable transparency of reporting, demonstrate how decisions were made about excluding citations and allow for easy replication and comparison of any future searches.

There is debate in the literature about the need for more than one researcher to undertake the initial screening of the citation titles and abstracts from the long list of search results (Levac et al., 2010; van den Berg et al., 2013). Since a scoping review retrieves, “all relevant data regardless of study design,” potentially thousands of results could be obtained (Arksey & O’Malley, 2005 pp.20). Due to resource and time constraints the author proposes that the first screening of the citation title and abstract will be carried out by one independent researcher (RH) for this review. Since the initial screening must meet the inclusion criteria for example; include the population (child) and the intervention (animal); it is a straightforward process and any uncertainty means the citation can be retained as it will be reviewed and a decision made in subsequent screenings (Leenaars et al., 2012). Arksey & O’Malley (2005) retrospectively applied inclusion and exclusion criteria, so by the articulation of definitive inclusion and exclusion criteria for screening of results in the review justifies the rationale for one independent researcher carrying out the initial screening. A sample of citation titles and abstracts at the beginning, middle and final stages of the initial screening will be reviewed independently by a second researcher (TK) to add transparency and credibility to the screening process in line with other reviews reported (Daudt et al., 2013; Levac et al., 2010).

Stage 4. Data charting

The second stage of screening results will be carried out independently by two researchers (RH & TK) using a reporting checklist or data charting form as it is known by for scoping reviews (Levac et al., 2010; Peters et al., 2017). A sample of ten studies charted independently by both reviewers will be compared and discussed to pilot the tool and assess if results are consistent with the research question. This approach was advocated by Daudt et al. (2013) to improve charting of results so that the review question can be answered appropriately. Citation titles and abstracts included in the second screening will be full text results which will be shared with each reviewer through Endnote. This strategy has been reported in the literature as being an effective method (Daudt et al., 2013). A third reviewer (CD) will be available to discuss any differences or ambiguities in results. A sample data charting form; adapted from the Cochrane collection template and informed by Nicholson et al. (2019); is attached as Table 2. Since the process of scoping reviews is an iterative process so too will be the need to discuss the suitability of the data charting form once screening has commenced and is discussed by the review team. Any changes to the form will be noted in the researcher’s research diary along with any decisions about screening as a result of any meetings, reflections and actions taken (Boland et al., 2017; Daudt et al., 2013).

Stage 5. Collating, summarising and reporting the results

Each data charting form will be given a unique number to aid identification and discussion across the review team as advised by Daudt et al. (2013). A description and summary of the review findings will be the form of analytical interpretation of the review results which will be enhanced through discussion with the review team and supervisor to draw out meaningful results (Vijayamohan, 2015). Peters et al. (2020) are definitive in stating that, “qualitative content analysis in scoping reviews is generally descriptive in nature” and therefore this review protocol will be in keeping with the Joanna Briggs Institute most recent publication. The use of innovative charting tools such as word clouds will be considered to visually represent definitions of animal assisted activities as an example. Other charted results will require more traditional narrative analysis as discussed by Levac et al. (2010).

Assessment of methodological quality

Traditionally the appraisal of methodological quality and risk of bias of the included articles are not consistent within the conduct of a scoping review (Levac et al., 2010). Therefore, the methods of each individual article will be charted only and the researcher will report the methodologies utilised throughout the discussion and synthesis of findings in the final report of the review.
The research team (SN) has expertise in the area of animal welfare and will be key to guiding and ensuring that the welfare of animals as well as research participants will be considered throughout the project.

Key collaborators will include animal handlers and volunteers from agencies which provide an animal visitation service to hospitals such as the Irish charity, Peata. These types of organisations can provide local knowledge and expertise in relation to current projects and research being carried out currently that may not yet be available through the public domain. Professional healthcare staff in the children’s hospitals who have already expressed an interest in the project and staff considered to be gatekeepers such as consultant, nursing administration, clinical nurse managers and the infection prevention and control team will be initial contacts to review the findings and give feedback to the research team once the scoping review has been completed. The play specialists working with children in the hospital have also expressed a keen interest and enthusiasm for the research. Children and young people who have had experience of hospital care represented by the national voluntary children’s youth advisory group YAC and the Ombudsman for Children’s Office will be contacted and arrangements made to share the review findings in a suitable medium for both groups of young people. Contact will only be made with these groups following full ethical approval. The primary author will make contact with the individual manager of these charities, hospitals and youth groups firstly by telephone, then by email/letter and confirmation of meeting dates, times and venues to share review findings. A summary document of the review findings will be shared prior to the first meeting so that initial feedback may be possible from the participants early in the process before any further discussions or plans are made.

Dissemination plans for completed scoping review
A range of dissemination strategies will include sharing of review findings with local academic networks within the authors’ place of work and third level institution. Oral and poster presentations at national and international conferences such as U21 Research in Healthcare and the International Society for Anthrozoology (ISAZ) have already shown interest in the research question and future review findings. The next ISAZ conference is to be held in Buffalo, New York, June 2021.

**Study status**
This study is at Stage 2 – Identification of relevant studies. A review of reference management software has begun with a preliminary incorporation of search terms into the search engines cited.

**Discussion and conclusion**
A scoping review protocol has been outlined and discussed in relation to the current literature and evidence available (Daudt et al., 2013; Levac et al., 2010; Peters et al., 2017 & Peters et al., 2020). The rationale for choosing a scoping review over any other type of review is clear since the

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**Table 2. Data charting form.**

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<td>Rationale for intervention (i.e. pain/anxiety)</td>
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<td><strong>Methods</strong> (if applicable)</td>
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<td><strong>Outcomes/ Recommendations</strong></td>
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Follow-up Required Yes No Contact details:
need for mapping the scientific evidence for AAI in children’s hospitals is required to inform any further research. From the initial search; carried out early 2020; mixed methods studies and systematic reviews on the topic of AAI were reported. However, the findings revealed a lack of consistency in research approaches and a need for a scoping review is warranted so that any further research can be planned appropriately to address any gaps in the scientific knowledge.

Data availability
Underlying data
No data are associated with this article.

References


Open Peer Review

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This review is written by Gail Davison, a senior paediatric trainee and PhD student, who has used scoping review to research the experience of sick children in hospital and Tim Dornan, former internist and education researcher. We share an interest in qualitative methodologies and, specifically those that give insight into sick people’s experiences in order to improve healthcare.

The protocol addresses an extremely important topic (non-pharmacological interventions to improve illness experience) which is all the more important because animal assisted activities are an interesting, unconventional type of therapy. The critical comments that follow are not at all intended to discourage the authors from conducting the review, but they are informed by GD’s experiences of scoping review, which might help the authors focus their work and have the greatest positive impact on children and parents.

If this protocol does one thing, it illustrates the shortcomings of scoping reviews. It assumes that some circumscribed topic already exists, that there is a clearly defined thing called ‘evidence’ which bears on the topic, and that a gap in the evidence can be identified by assembling it. What this protocol illustrates is that, certainly regarding animal assisted activities, that is far from the case. As a result, the protocol is somewhat lacking in focus and clarity.

In such an under-researched topic as this, there is a problem unanticipated by the Arksey and O’Malley framework: you first have to frame the topic in order to render it reviewable. Putting it more simply, if you simply round up the evidence, you will find it hard to decide what is and isn’t evidence and will end up with a hotchpotch of information that can really only lead you to the conclusion that “more research is needed”. We propose that the authors could do an extremely useful job by taking the vital step before that: clarify the field of inquiry. If you don’t have any idea what you want to do for children and why, then, you will have no idea whether you should be
interested in salivary cortisol levels or children missing their own pets. So, we suggest that a clearer definition of the field, which might clarify the possible impacts and their relative importance will make the selection and analysis of articles a lot easier and a lot more useful. The comments that follow turn those rather vague critical comments into more specific issues, which we hope will help the authors do what we suggest.

Purpose
Is this to gather evidence on what activities are being practised and how they influence children? Is it to explore why and how activities benefit children? Is it to understand under what conditions they are successful? Is it to examine which types of pets are most efficacious? Is it to improve experiences, or improve physiology and biochemistry? To show why we ask these questions, we draw the reviewers' attention to the first line of their review question. What do they mean by “science”, and what do they mean by “evidence base”? You will see that the answers to those questions will be completely different if you think salivary cortisol or the experience of being sick is more important. To give an example of this point, GD's scoping review uses children's verbatim accounts of their experiences as evidence and gives a careful justification for doing so. People who care about salivary cortisol would likely dismiss this evidence as fluffy and would find it hard to understand why we would dismiss salivary cortisol as irrelevant. Scoping reviewers need to come off the fence about this or, at least, acknowledge that there is a fence to come off. The reviewers show their own unclarity about this by flipping between the terms “activity” and “intervention”. It might clarify their own minds if they used examples to clarify their own position. GD draws attention to the limited way this has been done in the protocol by drawing attention to a previous critical review of AAIs in children's hospitals, which the reviewers do not quote.

For whom?
Another important question is who the beneficiaries of AAIs should be. Is it children alone? Is it children and parents? Could it even be parents? We suggest that, in paediatric research, authors should clarify their position on whether children are autonomous individuals or part of a "unit" of which their parents are an inevitably dominant part. Whilst it would be possible to look at all 3 parties (children, parents and HCPs), this would broaden the focus and limit the amount that could be said about children.

Risk
We suggest that it would be a missed opportunity if the issue of risk were not addressed. The reviewers write about AAIs in intensive care units. Would a dog have to wear PPE in that setting? What would happen if it wanted to spend a penny? When it comes to implementing the findings of this review, those might be the single most important issues for implementors. Are virtual interactions in scope?

Specific comments regarding the stages of scoping review:
Stage 1
We note that aims 1 and 2 are very little different from one another and would be appropriately placed with the research question. The heading 'protocol' could be removed. We suggest that terms like “children”, "AAI", and "Children's Hospital setting" need to be defined, otherwise it will be hard to decide which articles are in or out of scope. Rather than seeking 'scientific evidence', we suggest either asking 'what is known about animal assisted interventions for children and young people in children's hospital settings?' (leaving it open to unpublished evidence and grey literature) or ‘what is known about the scientific evidence base for ...?’ (therefore, including
research findings only). The sentence commencing ‘The population (P)…’ is unnecessary as it is self-explanatory.

Stage 2
The protocol is ambiguous regarding translation of non-English studies. The authors say that studies will be translated if they are valuable, but how can you know they’re valuable if you haven’t translated them? The protocol leaves it quite unclear how comprehensive the selection of articles will be. We suggest there is a real risk that the reviewers will be flooded by including grey literature, websites, and 14 databases with no limits on article types. The risk of being overwhelmed is made greater by the search strings, which are quite non-specific. We suggest a combination of MESH term searches and keyword searches (including compatible truncation, possibly locating keywords separated by 5-10 consecutive words).

Stage 3
We suggest that the eligibility criteria and limits are insufficiently defined to make the process as straightforward as the primary author suggests. Since there is a risk of being overwhelmed by gathering all information, it might be helpful to give an example of what a highly relevant (gold standard) article might look like. Of course, these issues could be addressed by iterative focusing of the review, rather than addressing them at this stage, but there is a real danger that the reviewers might irretrievably lose focus before they ever became clear.

Stages 4 and 5
We have no comments about these.

Stage 6
This stage is described rather generally in terms of networking, PPI and dissemination of findings, whereas Arksey and O’Malley intended stage 6 to be a formal consultation exercise, for which research ethics and governance approvals would be needed. We suggest that the authors should be clearer about this.

Discussion and conclusions
As it stands, these are rather bland. We hope that our preceding comments will give the reviewers some ideas about strengths, limitations, suspected challenges, and ways of addressing these that might strengthen the discussion and conclusions.

We have some other small suggestions:
The title uses the term “animal assisted activities”, which is different from the abbreviation AAI. Certainly, the authors should be consistent. We think intervention would be the more appropriate term to use because an intervention is implemented for an intended outcome, where an activity could be purely for its own sake. The phrase “at home in Ireland” and primarily quoting Irish studies may be of primary interest to the authors, but this orientation towards the country in which research was done would not be so persuasive to editors and reviewers of influential journals.

In summary, we appreciate that our comments may seem rather overwhelming. Actually, the message is rather simple. For your own sake, as well as for the sake of good scholarship, focus and be clear. Our comments are intended to help you do that.
Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Care of hospitalised children; scoping review; research methodology; medical education.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 22 Apr 2021

**Rachel Howe**, University College Dublin, Donnybrook, Ireland

Thank you Dr Dornan and Ms Davison for your time and valuable comments on our scoping review protocol. We have revised our protocol to reflect a more focused review question and take onboard your constructive criticism. We want to review the scientific evidence base for Animal Assisted Interventions (AAI) in children and young people who are inpatients in the children's hospital. The authors acknowledge that ‘science’ and ‘evidence base’ are sometimes loosely and liberally applied. In our protocol it means a map of the existing literature available through peer-reviewed journals irrespective of the quality. We also want to probe the literature to determine; Why has AAI been used? Where? And how effective was it? Were there implementation considerations? Were there particular research methods utilised and recommendations for future research?

Since the topic of AAI is relatively new in children's healthcare; indeed it is only recognised in academic circles since the beginning of the 21st Century (DeMello, 2012); there is a need to scope out the research undertaken internationally and map the evidence using the bespoke data charting form designed. The international scale of AAIs are important and hence the inclusion of non-English literature that meets the inclusion criteria. The review team possesses international language skills to enable the translation of title and abstracts in the first screening process. There is ambiguity in the international literature in relation to the definition and adaptation of the terms AAI (which is the umbrella term) animal assisted activities (AAA) and animal assisted therapy (AAT). Some studies use either concept or use them interchangeably. The subsequent scoping review will provide a clear definition of these terms from the literature. The scoping review will be undertaken to help frame and
focus further research. The main focus of the research will be on the children and young people, their responses to and interactions with AAI. We acknowledge that parents/guardians and healthcare providers act as gatekeepers for minors with regards to consent and access for research. Their input and opinions about the child or young person's reaction to the AAI will be important and valuable data to consider later when planning the research methods. Evaluating the responses of parents/guardians and healthcare providers of the AAIs would be another avenue of research which could be recommended for future research but not the focus of this study. However, studies reporting views other than children will not be excluded from this review since very few studies report just the children's views, and those that do, may not be reported separately.

The protocol stated that the research team includes a librarian (DS) with expert experience in carrying out searches using thesaurus tools and will provide assistance and support to the researcher carrying out the database searches. AAIs stem from the overarching discipline of Human-animal studies, which includes an array of multidisciplinarians and interdisciplinarians, justifying the need for searching so many databases. The highly sensitive search strategy using boolean operators, both free-text and subject headings (including MeSH when available) for each database search will be reported to ensure transparency through a clear audit trail. The keywords for each search string were clearly articulated in the protocol (Table 1.). The review team have also invested in Covidence for ease of screening and tracking decisions made on inclusion and exclusion criteria.

In relation to any potential risks; of bites or cross infection between animal and patients; there will be a need to ensure relevant policies and guidelines are implemented prior to AAI taking place. Additional content on these risks has also been included within the updated review protocol. Therefore, hopefully these reservations will now be alleviated.

**Competing Interests:** No competing interests were disclosed.

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**Reviewer Report 06 January 2021**

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Mary Hughes

Children's Nursing, School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland

Thank you for inviting me to review this very interesting manuscript. It is a novel topic and the rationale for the development of the protocol is presented in a clear and coherent manner. The development of the protocol follows a recognised framework and is based on the authors' understanding of the problem under investigation.
I suggest some minor changes to the manuscript, there are some errors in grammar and syntax which could be corrected with proof-reading. Some editing is required to reduce the duplication of information, and support the rationale for decisions made in the steps of the framework with reference to the literature.

I look forward to reading the report on the scoping review of the literature.

**Is the rationale for, and objectives of, the study clearly described?**
Yes

**Is the study design appropriate for the research question?**
Yes

**Are sufficient details of the methods provided to allow replication by others?**
Yes

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Child Health and Wellbeing, Chronic Illness in Childhood, Children's nursing.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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Author Response 22 Apr 2021

**Rachel Howe,** University College Dublin, Donnybrook, Ireland

Thank you Dr Hughes for taking the time to review our scoping review protocol. We appreciate your positive feedback. We will proof-read the subsequent protocol more carefully to reduce duplication of information and amend any grammar or syntax errors. Thank you again for your interest and constructive comments.

**Competing Interests:** No competing interests were disclosed.

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