PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Study protocol: A mixed-methods investigation of barriers and needs in mental healthcare of adults with autism and recommendations for future care (BarrierfreeASD)
AUTHORS	David, Nicole; Dückert, Sophia; Gewohn, Petia; König, Hannah; Rahlff, Pascal; Erik, Frank; Vogeley, Kai; Schöttle, Daniel; Konnopka, Alexander; Schulz, Holger; Peth, Judith

VERSION 1 – REVIEW

REVIEWER	Hull, Laura University College London
REVIEW RETURNED	19-May-2022

GENERAL COMMENTS	I very much enjoyed reading the protocol for this wide-reaching study to identify barriers and needs in mental healthcare for autistic adults. The protocol is well-written, concise, and convincing; describing a clear and pressing need for this work to be done while remaining realistic about what can be achieved through the present study. I have a few minor comments concerning the reporting of the protocol, but no strong concerns about the study design itself. 1. The title and focus of the study are on mental health, however much of the introduction seems to refer to more general healthcare for autistic adults. It would be good to have some more detailed description of potential factors that may be specific to mental healthcare rather than/in addition to general healthcare for autistic people. 2. I had a few minor queries around recruitment of participants. Firstly, it was not clear professionals included in Phases 1 and 3 would be recruited based on their level of experience or expertise in autism. I imagine that professionals' own needs, and their awareness of the needs of autistic people, will be influenced by how much they (knowingly) interact with autistic patients as part of their service provision. Have the authors considered how to ensure a range of levels of experience with autism (i.e. including professionals who work in autism-specific services, and those working in more general mental healthcare who have not had any autism-specific training)? How might this impact the conclusions and practical impact of the study? 3. Secondly, the authors state that they aim to over-recruit in order to compensate for anticipated drop-out. It would be useful to know the estimated drop-out rate; what is the minimum number of participants needed for the planned analyses, and do the authors have any contingency plans if recruitment targets are not met? 4. There is a good integration of health economic and community impact throughout the evaluation, making it more likely for findings to be actually implemented in healthcare services. Implementation

	itself is not part of the study, but the findings will form important groundwork for future implementation of models produced from the study. 5. I'm not an expert in health economics but I appreciate the inclusion of direct and indirect costs, including those incurred by family members. I wonder if it is worth also comparing to other disabled groups (or populations with mental health conditions) to identify if there are specific costs associated with being autistic and engaging with mental health services, compared to the costs of mental health issues for neurotypical people. 6. Dissemination – will study participants (particularly autistic people and their relatives) be informed of the findings? It is not clear whether participants who take part in Phase 1 will be re-recruited for Phase 3; if not, will they get a chance to learn about or express their opinion on the findings?

REVIEWER	Tucker, Sharon The Ohio State University
REVIEW RETURNED	20-May-2022

GENERAL COMMENTS	This manuscript presents a 3-phased study protocol for a mixed-methods study under way that is investigating barriers and needs in mental healthcare of adults with autism and developing recommendations for a healthcare model for future care. The study takes place in Germany and will involve enrollment of adult individuals diagnosed with autism, family or caregivers of individuals diagnosed with autism, and healthcare providers. Key stakeholders from professional relevant organizations are also involved in the study. The strengths and limitations of the study are outlined in the protocol. I have no real concerns with the protocol as it meets the SPIRIT guidelines for study protocols. A few minor comments/questions: 1) On page 7, a run-on sentence is included in line 32 with the first "i" bullet. 2) Are health insurances considered policy makers? Page 11, line 55. 3) On page 12, line 46, there seems to be a missing word or phrase "(e.g.,). 4) On page 13, line 48, statement to determine healthcare-related predictors....Please add predictors of what for the regression analyses. 5) Few typos such as health misspelled in article summary on page 4, line 36. Research is misspelled on page 16, line 41. A comma is also needed in that same sentence after the word "here". 6) In the SPIRIT checklist, item 18a asks about known validity and reliability of the instruments. This is not clear in the protocol. Seems item 19 Data management should include the page number as this is included in the protocol. Item 27 should also include page numbers as the team is assessing personal information from individuals about their healthcare. What specific items to be collected is not included in the protocol as it will be iteratively decided based on literature review.

REVIEWER	Schiltz, Hillary Marquette University
REVIEW RETURNED	12-Jun-2022

GENERAL COMMENTS	Thank you for the opportunity to review the protocol entitled Study protocol: A mixed-methods investigation of barriers and needs in mental healthcare of adults with autism and recommendations for future care (BarrierfreeASD). This study involves three phases each with corresponding goals. More specifically, the study aims to utilize qualitative and quantitative methods to 1) analyze healthcare needs/barriers for autistic adults, 2) develop a model with specific recommendation, and 3) evaluate future implementation of this model. The topic of this study is under-researched and important, and I believe this study will address a need in the literature and healthcare more broadly. The study is well-designed and the protocol is well-written. I have outlined the justification for each review question below. My primary concerns at this time center upon clarifying the scope of the study (i.e., all types of healthcare or solely mental healthcare) and further description of the data analytic plan. Please also find additional minor comments below for consideration that would strengthen the study. 1. Is the research question or study objective clearly defined? No. Although the authors clearly describe three primary goals of the study (i.e., analyzing the state of healthcare needs and barriers for autistic adults, developing a future model of healthcare, and evaluating future implementation of the model), I found the scope of the study to be unclear. In particular, in some places throughout the manuscript (including the title), the author state they are specifically exploring mental healthcare. In contrast, the introduction includes discussion of physical healthcare (e.g., medical conditions, vaccinations, checkups) and the participants from healthcare services include a wide range of professions including primary care, pediatrics, occupational therapy, physical therapy, medical care, etc. It is unclear if these providers will be discussing their specific services (e.g., physical therapy) or focusing solely on mental health. I encourage the authors to clarify throughout the manuscript if they will be focusing specifically on mental healthcare or a combination of mental and physical healthcare more broadly. 2. Is the abstract accurate, balanced and complete? Yes. My only recommendation in the abstract is to include the geographic location of the study. 3. Is the study design appropriate to answer the research question? Yes, the authors use a combination of quantitative and qualitative research methods that are appropriate. 4. Are the methods described sufficiently to allow the study to be repeated? Yes, the authors provide sufficient methodological detail. 5. Are research ethics (e.g. participant consent, ethics approval) addressed appropriately? Yes, research ethics are adequately addressed. 6. Are the outcomes clearly defined?

No. For the quantitative component of this mixed-method study, it is unclear which variables will be outcomes and which will be predictors. Please clarify the constructs, specific variables, and measures that will be utilized as the outcomes.

7. If statistics are used are they appropriate and described fully?

No. Related to question 6 above, the authors state that multiple regression analyses will be applied to “determine potential healthcare-related predictors” (pg. 13). Please list exactly which variables will be included as predictors and outcomes. I also encourage the authors to consider utilizing multi-level modeling given the potential nested structure of their data.

The authors state that they will “perform statistical group comparisons between subsamples” (pg. 13). Please clarify which subsamples will be compared and on which variables. Perhaps a table or figure may be useful to summarized proposed quantitative analyses.

8. Are the references up-to-date and appropriate?

Yes, the references are appropriate and up-to-date.

9. Do the results address the research question or objective?

N/A

10. Are they presented clearly?

N/A

11. Are the discussion and conclusions justified by the results

N/A

12. Are the study limitations discussed adequately?

Yes, at this stage, the authors have discussed the major identifiable limitation related to not implementing and testing the model. Further limitation should be noted following study completion (e.g., depending upon the sample composition, whether the sample is representative or not).

13. Is the supplementary reporting complete (e.g. trial registration; funding details; CONSORT, STROBE or PRISMA checklist)?

Yes, the authors have completed the SPIRIT Checklist.

14. To the best of your knowledge is the paper free from concerns over publication ethics (e.g. plagiarism, redundant publication, undeclared conflicts of interest)?

Yes, to my knowledge this paper adheres to publication ethics.

15. Is the standard of written English acceptable for publication?

Yes, the manuscript is very well-written and easy to follow.

	Other comments for consideration - Please clarify if the review (phase 1) will be a systematic review of the literature or a scoping review. If it is a systematic review, please be sure to provide all relevant details (e.g., search terms, inclusion/exclusion criteria, number of source identified, specific databases searched, etc.). Please also clarify if this review will focus on a particular geographic region of services or if it will include studies conducted internationally. - Given that the authors intend to create novel online survey instruments, it may be worthwhile to also include some psychometric exploration of these questionnaires to further bolster the methodological foundation of the study. - Should the authors focus on mental healthcare specifically, I would encourage the authors to include some discussion of the rates of various mental health conditions and to highlight that autistic adults are more likely than non-autistic adults to experience mental health concerns. - Please review document for typographical errors.

VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments and replies:

Reviewer 1 (Dr. Laura Hull, University College London)

I very much enjoyed reading the protocol for this wide-reaching study to identify barriers and needs in mental healthcare for autistic adults. The protocol is well-written, concise, and convincing; describing a clear and pressing need for this work to be done while remaining realistic about what can be achieved through the present study. I have a few minor comments concerning the reporting of the protocol, but no strong concerns about the study design itself.

Author response: Thank you!

1. The title and focus of the study are on mental health, however much of the introduction seems to refer to more general healthcare for autistic adults. It would be good to have some more detailed description of potential factors that may be specific to mental healthcare rather than/in addition to general healthcare for autistic people.

Author response:
We agree with the reviewer’s assessment and have taken several steps in order to address her comment (please also compare to Reviewer 3).
First, we now use more consistent and precise wording throughout the entire manuscript, referring to “mental healthcare” when indicated.
Second, we restructured and added information to the introduction. For example, with respect to the scope of the study we now explain (p. 7): “While the focus of the study is on mental healthcare (i.e., particularly, diagnosis, therapy and supportive services), the study will also examine all health-related services relevant for autistic adults given the afore-mentioned complexity of the condition.”
Moreover, we added information specific to mental healthcare in ASD. For example, we now write (p. 4/5): “rates of mental health comorbidity were found to be particularly increased in adults with autism (i.e., more than 80% of patients showed psychiatric comorbidity)[8], including anxiety disorders and

mood disorders but also sleep disturbances, ADHD, even psychosis[5]. These conditions were related to reduced quality of life in autistic adults[9 10], suggesting a particular need for mental health services." We further elaborate (on p. 4/5): "Despite this need, observations of ineffective or cost-inefficient healthcare utilization have been made for autistic adults with respect to primary or medical healthcare such as preventive services, gynecology, urgent care or emergency department visits [7 8 11 12] but also to mental health services such as psychiatric, therapeutical, counselling, psychopharmacological or other supporting services [12-18]. Medical and mental health comorbidities in adults with autism were associated with increased barriers to service use [18] as well as healthcare expenditures[8]. Analyses of autism-related mental healthcare expenditures using data from psychiatric outpatient clinics in Germany revealed costs comparable to those attributable to schizophrenia[19]. Largest cost components arose from inpatient care, pharmacotherapy and occupational therapy, and costs varied as a function of gender, IQ and diagnosis."
Additional references:
12. Ames JL, Massolo ML, Davignon MN, Qian Y, Croen LA. Healthcare service utilization and cost among transition-age youth with autism spectrum disorder and other special healthcare needs. Autism. 2021 Apr;25(3):705-718. doi: 10.1177/1362361320931268.
13. Schott W, Nonnemacher S, Shea L. Service Use and Unmet Needs Among Adults with Autism Awaiting Home- and Community-Based Medicaid Services. J Autism Dev Disord. 2021 Apr;51(4):1188-1200. doi: 10.1007/s10803-020-04593-2.
14. Lipinski S, Blanke ES, Suenkel U, et al. Outpatient Psychotherapy for Adults with High-Functioning Autism Spectrum Condition: Utilization, Treatment Satisfaction, and Preferred Modifications. Journal of Autism and Developmental Disorders 2019;49(3):1154-68. doi: 10.1007/s10803-018-3797-1
15. Croteau C, Mottron L, Dorais M, Tarride JE, Perreault S. Use, costs, and predictors of psychiatric healthcare services following an autism spectrum diagnosis: Population-based cohort study. Autism. 2019 Nov;23(8):2020-2030. doi: 10.1177/1362361319840229.

2. I had a few minor queries around recruitment of participants. Firstly, it was not clear professionals included in Phases 1 and 3 would be recruited based on their level of experience or expertise in autism. I imagine that professionals' own needs, and their awareness of the needs of autistic people, will be influenced by how much they (knowingly) interact with autistic patients as part of their service provision. Have the authors considered how to ensure a range of levels of experience with autism (i.e., including professionals who work in autism-specific services, and those working in more general mental healthcare who have not had any autism-specific training)? How might this impact the conclusions and practical impact of the study?

Author response: We thank the reviewer for pointing out these missing details that we are now happy to provide. Indeed, we aimed at assessing a wide range of perspectives and levels of professional experience with autism in order to gain a comprehensive picture of barriers and needs in healthcare of autistic adults. The reviewer is correct that there is good reason to believe that professional barriers and needs might be different depending on their professional background, setting and experience with autism. Thus, we revised the corresponding methods section and now write (p. 8): "For qualitative data collection (i.e., focus groups), we will primarily recruit providers of mental healthcare services with experience in treating patients or clients with autism in order to gain central information about the current state of mental healthcare, including barriers and needs, for autistic adults in Germany and to support coherent discussions. Primary care practitioners and pediatrists will also be recruited due to their particular role in transition and coordination of care. Given the often complex health status and broad service needs of autistic adults as well as supposed barriers throughout the care system (e.g., due to lack of knowledge about autism), the large-scale online surveys will also include data from healthcare providers with various professional backgrounds and levels of experience with autism (from working in autism-specific services to more general services or no expertise in autism) in order

to gather a more comprehensive and representative picture on barriers and needs with respect to treating autistic adults and to examine whether qualitatively identified barriers and needs also apply to different healthcare settings."
In addition, we now explain (p. 9): "Inclusion of different professional backgrounds and levels of experience with autism along with other relevant criteria (e.g., geographic distribution, urban or countryside, etc.) will be ensured by pre-defined recruitment strategies and collection of corresponding sociodemographic data via questionnaire in the recruitment and data collection process."
Moreover, to further adress the reviewer's suggestion, for quantitative data from online surveys, we could investigate how professionals' ratings, e.g., on barriers and needs, might differ as a function of experience with autism.

3. Secondly, the authors state that they aim to over-recruit in order to compensate for anticipated drop-out. It would be useful to know the estimated drop-out rate; what is the minimum number of participants needed for the planned analyses, and do the authors have any contingency plans if recruitment targets are not met?

Author response: We have added the suggested information to the manuscript on p. 14 and have rewritten the corresponding methods section, which we hope has now improved. We now state: "Based on power calculation, a minimum of n=500 participants will be aimed at for each quantitative online survey. This sample size represents the minimum number of participants needed for group comparisons with at least medium effect sizes (d=0.50) at a power of 80% and an alpha error of 5%. Previously published related online surveys with autistic participants or caregivers have reported dropout rates of 15% to 35% due to reasons such as incomplete or duplicate responses, failure to consent or to meet inclusion criteria[52 53]. Thus, here to compensate for dropouts, participants will be over-recruited (i.e., a dropout rate of 15% would correspond to 75 additional participants). The motivation to participate in scientific studies can be considered high in the autism community, particularly regarding participation in online surveys and research with impact to their everyday life. Yet, if recruitment targets are not met, the following steps will be taken to achieve planned sample sizes: extension of the data collection time window, increased networking as well as enhanced promotion of our research via associations, social media and community outreach."
References:
52. Pellicano E, Dinsmore A, Charman T. What should autism research focus upon? Community views and priorities from the United Kingdom. Autism 2014;18(7):756-70. doi: 10.1177/1362361314529627
53. Weir E, Allison C, Baron-Cohen S. Autistic adults have poorer quality healthcare and worse health based on self-report data. Mol Autism. 2022 May 26;13(1):23. doi: 10.1186/s13229-022-00501-w. PMID: 35619147; PMCID: PMC9135388.

4. There is a good integration of health economic and community impact throughout the evaluation, making it more likely for findings to be actually implemented in healthcare services. Implementation itself is not part of the study, but the findings will form important groundwork for future implementation of models produced from the study.

Author response: Thank you!

5. I'm not an expert in health economics but I appreciate the inclusion of direct and indirect costs, including those incurred by family members. I wonder if it is worth also comparing to other disabled groups (or populations with mental health conditions) to identify if there are specific costs associated

with being autistic and engaging with mental health services, compared to the costs of mental health issues for neurotypical people.

Author response: We thank the reviewer for bringing this up. Unfortunately, the comparison data set available at our Department of Health Economics and Health Services Research is based on data drawn from the general German population. According to the health economic experts in our research group, this comparison enables the analysis of all costs attributable to autism. Yet, we seek to adress the reviewer's suggestion by discussing our results in relation to health-economic evidence from other clinical populations. This is now explained on (p. 16): "The estimated costs for autistic adults will then be compared to the general German population, and excess costs will be calculated[58]. Under the assumption that differences in sociodemographic covariates or comorbidities across groups are adjusted, the excess cost approach enables the analysis of all costs attributable to autism. Based on the skewed distribution of cost data, cost differences will be calculated using generalized linear models with gamma distribution and log-link function. Our findings will also be compared to other evidence on cost-of-illness in autism and other mental health conditions such as depression as common mental disorder, schizophrenia as disorder with similar prevalence, or ADHD as other developmental disorder."

6. Dissemination –
Will study participants (particularly autistic people and their relatives) be informed of the findings?
It is not clear whether participants who take part in Phase 1 will be re-recruited for Phase 3;
if not, will they get a chance to learn about or express their opinion on the findings?

Author response:
We thank the reviewer for pointing out these missing details that we are now happy to provide in the corresponding sections. For example, we now write on p. 17 ("Patient and public involvement"): "Cooperation partners and all other study participants from focus groups and interviews will be offered to receive quarterly newsletters about the course and interim findings of the study. For all other participants (e.g., who anonymously took part in the online surveys), information will be made publicly available on a project website. Participants will be given the possibility to express feedback or concerns through the project's email-address or via direct contact to one of our (peer) researchers."
On p. 18 ("Dissemination"), we now also state: "Study participants from focus groups and interviews will also receive quarterly newsletters about the progression and outcomes of the study. Information, including study information, posters and presentations, will also be disseminated via the project's webpage."
With respect to the reviewer's question whether same participants will be recruited for Phase 1 and 3, we now provide more details in the methods section on p. 13 ("In Phase 3, participants from Phase 1 will be re-recruited or, if this is not possible, comparable representatives will be invited.")

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Reviewer 2 (Dr. Sharon Tucker, The Ohio State University)

This manuscript presents a 3-phased study protocol for a mixed-methods study under way that is investigating barriers and needs in mental healthcare of adults with autism and developing recommendations for a healthcare model for future care. The study takes place in Germany and will involve enrollment of adult individuals diagnosed with autism, family or caregivers of individuals diagnosed with autism, and healthcare providers. Key stakeholders from professional relevant organizations are also involved in the study. The strengths and limitations of the study are outlined in the protocol. I have no real concerns with the protocol as it meets the SPIRIT guidelines for study protocols. A few minor comments/questions:

1) On page 7, a run-on sentence is included in line 32 with the first "i" bullet.

Author response: We thank the reviewer for pointing this out. The run-on sentence has been modified.

2) Are health insurances considered policy makers? Page 11, line 55.

Author response: The reviewer is correct that health insurances cannot directly operate at the legislative level (i.e., the Federal Ministry of Health). Thus, we now simply write: “For policy makers, recommendations will focus on extended services to reduce structural barriers.”

3) On page 12, line 46, there seems to be a missing word or phrase "(e.g.,).

Author response: This has now been corrected.

4) On page 13, line 48, statement to determine healthcare-related predictors. Please add predictors of what for the regression analyses.

Author response: We thank the reviewer for her suggestion. We agree that our previous data analytic account was too brief. As requested, we now provide more methodological details and statistical information on outcomes, predictors and planned analyses throughout the methods section. Please also see reply to Reviewer 3 (comment #7).
We now write (p. 15): “In order to determine predictors of healthcare utilization of autistic adults in Germany and, thus, also inform the development of an extended care model in Phase 2 (e.g., indications for services[cf. 42]), multiple regression analyses will be conducted. The following variables will be tested as potential predictors, i.e., enabling or disabling healthcare utilization: sociodemograpic variables (e.g., gender, age, education), autism diagnosis, symptom severity/ level of required support according to DSM-5[3], comorbidity, and experienced barriers to healthcare as operationalized by the score on the “barriers to healthcare” questionnaire[29] as well as by ratings from our own online survey. With respect to the latter, a factor analysis will be performed in order to identify underlying dimensions. Scores of factors with the highest variance will then be used as predictors for regression analyses.”

5) Few typos such as health misspelled in article summary on page 4, line 36. Research is misspelled on page 16, line 41. A comma is also needed in that same sentence after the word "here".

Author response: Thank you, we carefully reviewed the manuscript and hope that all typographical errors have now been corrected.

6) In the SPIRIT checklist, item 18a asks about known validity and reliability of the instruments. This is not clear in the protocol. Seems item 19 Data management should include the page number as this is included in the protocol. Item 27 should also include page numbers as the team is assessing personal information from individuals about their healthcare. What specific items to be collected is not included in the protocol as it will be iteratively decided based on literature review.

Author response: We thank the reviewer for pointing out these missing details regarding the SPIRIT checklist. In accordance with the reviewer’s request and the SPIRIT checklist, we now write (p. 11):

“These represent previously validated instruments with good overall validity and reliability[29 43-45]”. Moreover, we now state that our own constructed items from the online surveys “will be explored with respect to psychometric properties, such as content and construct validity, discriminability and internal consistency, for example, via correlational or exploratory factor analyses. We will also examine floor and ceiling effects using descriptive analyses” (p. 11). Second, we have added information in the manuscript and page numbers with respect to SPIRIT items #19 (Data management) and #27 (Confidentiality).

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Reviewer 3 (Hillary Schiltz, Marquette University)

Thank you for the opportunity to review the protocol entitled Study protocol: A mixed-methods investigation of barriers and needs in mental healthcare of adults with autism and recommendations for future care (BarrierfreeASD). This study involves three phases each with corresponding goals. More specifically, the study aims to utilize qualitative and quantitative methods to 1) analyze healthcare needs/barriers for autistic adults, 2) develop a model with specific recommendation, and 3) evaluate future implementation of this model. The topic of this study is under-researched and important, and I believe this study will address a need in the literature and healthcare more broadly. The study is well-designed and the protocol is well-written.

Author response: Thank you!

I have outlined the justification for each review question below. My primary concerns at this time center upon clarifying the scope of the study (i.e., all types of healthcare or solely mental healthcare) and further description of the data analytic plan. Please also find additional minor comments below for consideration that would strengthen the study.

Author response: We thank the reviewer for her comments, which were very constructive and helpful in revising and improving the manuscript. We now emphasize the scope of our study, revised the introduction and added information to the data analytic plan as requested. Please find more details in our point-to-point replies below.

1. Is the research question or study objective clearly defined? No. Although the authors clearly describe three primary goals of the study (i.e., analyzing the state of healthcare needs and barriers for autistic adults, developing a future model of healthcare, and evaluating future implementation of the model), I found the scope of the study to be unclear. In particular, in some places throughout the manuscript (including the title), the author state they are specifically exploring mental healthcare.
In contrast, the introduction includes discussion of physical healthcare (e.g., medical conditions, vaccinations, checkups) and the participants from healthcare services include a wide range of professions including primary care, pediatrics, occupational therapy, physical therapy, medical care, etc. It is unclear if these providers will be discussing their specific services (e.g., physical therapy) or focusing solely on mental health.
I encourage the authors to clarify throughout the manuscript if they will be focusing specifically on mental healthcare or a combination of mental and physical healthcare more broadly.

Author response: We fully agree with the reviewer that the scope of our study was unclear. Several revisions have now been undertaken to address the reviewer’s comment (please also refer to Reviewer 1, comment #1).

First, we have now restructured and revised the introduction by explicitly describing the scope of our study, slightly toning down evidence on medical healthcare and adding evidence on mental health, e.g., rates of mental health conditions in ASD (also see reply to the last comment). For example, we now describe the scope of the study (p. 7, introduction): “While the focus of the study is on mental healthcare (i.e., particularly, diagnosis, therapy and supportive services), the study will also examine all health-related services relevant for autistic adults given the afore-mentioned complexity of the condition.”
Second, throughout the manuscript, we now use more consistent and precise wording referring to “mental healthcare” when indicated.
Third, with respect to recruitment of various professional backgrounds, we now specify (p.8, methods): “For qualitative data collection (i.e., focus groups), we will primarily recruit providers of mental healthcare services with experience in treating patients or clients with autism in order to gain central information about the current state of mental healthcare, including barriers and needs, for autistic adults in Germany and to support coherent discussions. Primary care practitioners and pediatrists will also be recruited due to their particular role in transition and coordination of care. Given the often complex health status and broad service needs of autistic adults as well as supposed barriers throughout the care system (e.g., due to lack of knowledge about autism), the large-scale online surveys will also include data from healthcare providers with various professional backgrounds and levels of experience with autism (from working in autism-specific services to more general services or no expertise in autism) in order to gather a more comprehensive and representative picture on barriers and needs with respect to treating autistic adults and to examine whether qualitatively identified barriers and needs also apply to different healthcare settings.”
Moreover, on p. 10 in the methods section, we now specify the topics, which will be discussed by participants in each the focus groups (“Three interview guides will be developed, tailored to each stakeholder group. Participants' experiences with healthcare or with provision of services/ treatment of autistic adults will be assessed. Barriers, facilitators, and needs in healthcare of autistic adults, especially with focus on mental healthcare (i.e., diagnostics, therapy and assisting services), at individual, professional, and structural levels and recommendations for improving mental healthcare for autistic adults will be discussed.”).
With these revisions, we hope that the description of scope and research rationale has now improved.

2. Is the abstract accurate, balanced and complete? Yes. My only recommendation in the abstract is to include the geographic location of the study.

Author response: We have now added “Germany” to our abstract.

3. Is the study design appropriate to answer the research question? Yes, the authors use a combination of quantitative and qualitative research methods that are appropriate.

Author response: Thank you!

4. Are the methods described sufficiently to allow the study to be repeated? Yes, the authors provide sufficient methodological detail.

Author response: Thank you!

5. Are research ethics (e.g., participant consent, ethics approval) addressed appropriately? Yes, research ethics are adequately addressed.

Author response: Thank you!

6. Are the outcomes clearly defined? No. For the quantitative component of this mixed-method study, it is unclear which variables will be outcomes and which will be predictors. Please clarify the constructs, specific variables, and measures that will be utilized as the outcomes.

Author response: We have now added methodological and statistical details throughout the methods section. Planned statistical analyses as well as dependent and independent variables or outcomes and predictors for each analysis are now explicitly defined (on p. 15). The revisions made are more detailed in our reply to the reviewer's next comment below (comment #7).

7. If statistics are used are they appropriate and described fully? No. Related to question 6 above, the authors state that multiple regression analyses will be applied to "determine potential healthcare-related predictors" (pg. 13). Please list exactly which variables will be included as predictors and outcomes.
I also encourage the authors to consider utilizing multi-level modeling given the potential nested structure of their data.
The authors state that they will "perform statistical group comparisons between subsamples" (pg. 13). Please clarify which subsamples will be compared and on which variables. Perhaps a table or figure may be useful to summarized proposed quantitative analyses.

Author response: In reply to the reviewer's helpful suggestions, we have substantially revised the data analyses section. On p. 15, we now write: "We will run descriptive statistical analyses and report frequencies/percentages, means/medians and standard deviations/interquartile ranges separate for each stakeholder group on, if applicable, (i) sociodemographic data (e.g., age, gender, education, employment status, profession), (ii) clinical data (e.g., diagnosis, comorbidities, service utilization), (iii) objective healthcare indicators (e.g., waiting times for or distances of services), (iv) subjective ratings on barriers and needs in mental healthcare (Phase 1) or evaluative ratings on implementation of the developed care model (Phase 3)[49 50], and (v) on implemented standardized questionnaires related to barriers to healthcare[29], health-related quality of life[43], disability and functioning[44], burden of care[45] and implementation[e.g. 51]. Primary outcome will be service utilization in the last six months as assessed in the online surveys and groups of autistic adults and relatives. In order to determine predictors of healthcare utilization of autistic adults in Germany and, thus, also inform the development of an extended care model in Phase 2 (e.g., indications for services[cf. 42]), multiple regression analyses will be conducted. The following variables will be tested as potential predictors, i.e., enabling or disabling healthcare utilization: sociodemograpic variables (e.g., gender, age, education), autism diagnosis, symptom severity/ level of required support according to DSM-5[3], comorbidity, and experienced barriers to healthcare as operationalized by the score on the "barriers to healthcare" questionnaire[29] as well as by ratings from our own online survey. With respect to the latter, a factor analysis will be performed in order to identify underlying dimensions. Scores of factors with the highest variance will then be used as predictors for regression analyses. In secondary, more exploratory, analyses, we aim to test for mean differences between stakeholder groups on subjective ratings of barriers and needs in mental healthcare (Phase 1) and evaluation/ implementation of the developed need-oriented care model (Phase 3), using stakeholder group as independent variable and ratings as dependent variable employing parametric or non-parametric statistical tests depending on scale level and data distribution.
Quantitative data will be tested statistically based on 95% confidence intervals."

Finally, we very much appreciate the reviewer’s suggestion to use multi-level modeling and will be happy to consider this methodological approach after testing for nested structures once data collection will be completed.

8. Are the references up-to-date and appropriate? Yes, the references are appropriate and up-to-date.

Author response: Thank you!

9. Do the results address the research question or objective? N/A

10. Are they presented clearly? N/A

11. Are the discussion and conclusions justified by the results? N/A

12. Are the study limitations discussed adequately? Yes, at this stage, the authors have discussed the major identifiable limitation related to not implementing and testing the model. Further limitation should be noted following study completion (e.g., depending upon the sample composition, whether the sample is representative or not).

Author response: Thank you!

13. Is the supplementary reporting complete (e.g. trial registration; funding details; CONSORT, STROBE or PRISMA checklist)? Yes, the authors have completed the SPIRIT Checklist.

Author response: Thank you!

14. To the best of your knowledge is the paper free from concerns over publication ethics (e.g. plagiarism, redundant publication, undeclared conflicts of interest)? Yes, to my knowledge this paper adheres to publication ethics.

Author response: Thank you!

15. Is the standard of written English acceptable for publication? Yes, the manuscript is very well-written and easy to follow.

Author response: Thank you very much for this assessment!

Other comments for consideration
- Please clarify if the review (phase 1) will be a systematic review of the literature or a scoping review. If it is a systematic review, please be sure to provide all relevant details (e.g., search terms, inclusion/exclusion criteria, number of source identified, specific databases searched, etc.). Please also clarify if this review will focus on a particular geographic region of services or if it will include studies conducted internationally.

Author response: We thank the reviewer for pointing this out. In fact, two literature searches to inform methodological development (with no plans to be published) and one systematic review on health-economic evidence in autistic adults (with plans to be published) will be carried out. This is now specified and explained in the respective methods sections (e.g., p.10: “a literature search on national and international evidence will be conducted in PubMed to identify previously published barriers, facilitators and needs related to healthcare and mental healthcare of adults with autism. Results will be used to develop guideline questions for qualitative data collection”). Moreover, for the planned systematic review we added the requested detail (excluding results such as “number of sourced identified”; on p. 16): “The systematic review will be carried out in agreement with the PRISMA guidelines. Standard databases such as Medline/ PubMed and PsycInfo as well as reference lists will be searched for international studies in English or German. The search term will focus on “costs of illness”, “health expenditures”, “cost effectiveness” or “cost analysis”, “burden of illness”, “economic burden” and “autism spectrum disorders”, combined with Boolean operators.”

- Given that the authors intend to create novel online survey instruments, it may be worthwhile to also include some psychometric exploration of these questionnaires to further bolster the methodological foundation of the study.

Author response: We thank the reviewer for her suggestion. We have now added the following information to the methods section (p. 11): “Online surveys, i.e., barrier- and needs-related items, will be explored with respect to psychometric properties, such as content and construct validity, discriminability and internal consistency, for example, via correlational or exploratory factor analyses. We will also examine floor and ceiling effects using descriptive analyses. As proxy for acceptability, we will examine patterns of missing data or low response rates.”

- Should the authors focus on mental healthcare specifically, I would encourage the authors to include some discussion of the rates of various mental health conditions and to highlight that autistic adults are more likely than non-autistic adults to experience mental health concerns.

Author response: We agree with the reviewer that our introduction was missing emphasis on mental health conditions in ASD and now include a discussion of mental health issues and comorbidities in ASD. For example, we now write (p. 4): “rates of mental health comorbidity were found to be particularly increased in adults with autism (i.e., more than 80% of patients showed psychiatric comorbidity)[8], including anxiety disorders and mood disorders but also sleep disturbances, ADHD, even psychosis[5]. These conditions were related to reduced quality of life in autistic adults[9 10], suggesting a particular need for mental health services. Despite this need, observations of ineffective or cost-inefficient healthcare utilization have been made for autistic adults with respect to primary or medical healthcare such as preventive services, gynecology, urgent care or emergency department visits [7 8 11 12] but also mental health services such as psychiatric, therapeutical, psychotropic medication or other supporting services [12-18]. Medical and mental health comorbidities in adults with autism were associated with increased barriers to service use [18] as well as healthcare expenditures[8]. Analyses of autism-related mental healthcare expenditures using data from psychiatric outpatient clinics in Germany revealed costs comparable to those attributable to schizophrenia[19]. Largest cost components arose from inpatient care, pharmacotherapy and occupational therapy, and costs varied as a function of gender, IQ and diagnosis. Asperger syndrome despite being considered “high-functioning” was associated with higher costs[19] and higher unmet healthcare needs[18].”

- Please review document for typographical errors.

Author response: The manuscript has again been carefully checked and typos were corrected.