PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Piloting of the virtual telecare technology 'Addison Care' to promote self-management in persons with chronic diseases in a community setting: protocol for a mixed methods user experience, user engagement and usability pilot study
AUTHORS	Krutter, Simon; Schuessler, Nadine; Kutschar, Patrick; Šabić, Edin; Dellinger, Johanna; Klausner, Tabea; Nestler, Nadja; Beasley, Morgan; Henderson, Bailey; Pitzer, Stefan; Mitterlehner, Barbara; Langegger, Doris; Winkler, Anna; Kloesch, Michael; Eßl-Maurer, Roland; van der Zee-Neuen, Antje; Osterbrink, Jürgen

VERSION 1 – REVIEW

REVIEWER	Birrell, Fraser University of Newcastle upon Tyne
REVIEW RETURNED	25-Mar-2022

GENERAL COMMENTS	This is a protocol paper for a mixed-methods feasibility study of a named avatar-based system for older people with a plan to enrol 20 patients. Major issues 1) I am not convinced that the complexity of design or size warrants a protocol paper, which is usually for major studies with a degree of complexity. 2) The language is inaccurate in places (for example, chronic diseases are not a trend: a change in them would be) and vague in others (which standardised instruments?) 3) It is a shame patients were not involved in 'development of the research question, outcome measures and the design of the study'. I think they should be. Minor issues Not listed in view of above. Conclusions I don't think this small feasibility study justifies a protocol publication. This is one case where the findings should be included.

REVIEWER	Ye, Zhihong Zhejiang University School of Medicine Sir Run Run Shaw Hospital
REVIEW RETURNED	05-Apr-2022

GENERAL COMMENTS	Thank you for the opportunity to review this paper. I offer the following suggestions to help enhance the paper and its presentation to readers. Background

	1. The background is too long and it should be shortened. 2. In this sentence, “Research concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results [16-18].”, “Research” should be revised as “researches”. Methods and analysis 1. Included criteria and excluded criteria should be separated. 2. Specific setting should be provided. 3. Provide intervention content. 4. The interview guide questions should be provided. 5. In “standardized research instruments” part, supplement the Cronbach value and scoring method of every instrument. 6. In this study, the sample size of qualitative study depends on the thematic saturation. Therefore, the sample size of 20 may be not enough for qualitative study. Discussion 1. The discussion section should be deepened. 2. Supplement the significance of the study. 3. Advise to supplement the challenges of this study. 4. Supplement the strengths of the study. On the whole, the paper is well-written, but if you could get a native English speaker to edit your text, it should make parts of it a bit clearer.

REVIEWER	Roets-Merken, Lieve Radboud University Nijmegen, Radboud Institute for Health Sciences, IQ Healthcare
REVIEW RETURNED	05-Apr-2022

GENERAL COMMENTS	Overall, this protocol is transparent and well-designed, and in line with the SPIRIT criteria. The study aims to explore the feasibility of a culturally adapted intervention, but the authors don’t call it a feasibility study. The authors’ choice for the UTAUT framework has as consequence that the terminology and concepts of the primary outcomes don’t match with the in qualitative research more widely spread feasibility concepts and terminology. There is nothing wrong with using the UTAUT framework, but the authors should avoid an inconsistent mix: in the title, abstract and discussion, the authors stick to their three primary outcomes (experience/usability/user engagement), but in their objectives they add concepts such as feasibility and acceptability, probably taken from the more usual frameworks on feasibility? Consequently, the concepts loose transparency, with an augmented risk of bias in data analysis and interpretation. As the study will start soon, I recommend that the authors (1) stick to their three primary outcomes and (2) incorporate the knowledge and experiences of other feasibility frameworks into their data analysis. On page 13, lines 33-34, they mention that they will use deductive codes prepared from theoretical pre-considerations. I recommend to consider to adding codes here that are based on the key areas of e.g. the framework of Bowen (How we design feasibility studies 2009) which includes several key area’s that `I believe may be valuable in this study, such as demand (basic criterion when aiming at self-management), acceptability and practicality.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1, Dr. Fraser Birrell, University of Newcastle upon Tyne:

Comment	**Response**
1) I am not convinced that the complexity of design or size warrants a protocol paper, which is usually for major studies with a degree of complexity.	In addition to the design of a user experience, user engagement and usability study, this protocol describes the intervention of a novel and culturally adopted virtual telecare technology to assist patients with a chronic disease in their self-management in a community setting. Furthermore, this study is framed by a multifaceted theoretical model of health tecnology acceptance. And, as a pilot study, we see additional value in publishing the protocol for an efficient planning of the subsequent main study. Studies of similar design also published a protocol and described their procedures for the critical appraisal of the audience. E.g.: Vaughn J, Summers-Goeckerman E, Shaw RJ, Shah N. A Protocol to Assess Feasibility, Acceptability, and Usability of Mobile Technology for Symptom Management in Pediatric Transplant Patients. Nurs Res. 2019;68(4):317-23. Giunti G, Rivera-Romero O, Kool J, Bansi J, Sevillano JL, Granja-Dominguez A, et al. Evaluation of More Stamina, a Mobile App for Fatigue Management in Persons with Multiple Sclerosis: Protocol for a Feasibility, Acceptability, and Usability Study. JMIR Res Protoc. 2020;9(8):e18196.
2) The language is inaccurate in places (for example, chronic diseases are not a trend: a change in them would be) and vague in others (which standardised instruments?)	Thank you for pointing out this inaccuracy. We have now replaced the term “trend” by the term “challenge”. Moreover, standardized instruments employed in the current study are now listed as part of the abstract section. (see page 2)
3) It is a shame patients were not involved in ‘development of the research question, outcome measures and the design of the study’. I think they should be.	Since the present study is a user experience, user engagement and usability study, the research question and outcomes are pre-designed. Nevertheless, our study follows the approach of a User-Centered Design. By which the results of the UX Research and the identified needs of the users will be implemented in the further development of the virtual telecare technology “Addison”. In this respect, the mixed-methods design is aimed to provide rich information on the subjective experience of the patients in their usage of the technology. Per definition, the main focus of the current study is on patients

	and the outcomes of the current study are essential in the development of a clinical trial.
Minor issues Not listed in view of above. Conclusions I don't think this small feasibility study justifies a protocol publication. This is one case where the findings should be included.	We thank the reviewer for their estimation. Considering our response provided above, we hope to have convinced them of the relevance of our study and the publication of its study protocol.

Reviewer 2, Dr. Zhihong Ye, Zhejiang University School of Medicine Sir Run Run Shaw Hospital:

Comment	**Response**
Background 1. The background is too long and it should be shortened.	We acknowledge the relevance of a concise yet informative background section. Following the reviewers feedback, we have shortened the manuscript on the topic of Remote Patient Monitoring (RPM) in the background.
2. In this sentence, "Research concerning the efficacy of RPM has spanned the topics of post-operative rehospitalization, chronic disease management, medication adherence, and quality of life and has shown promising results [16-18].", "Research" should be revised as "researches". Methods and analysis	We thank the reviewer for pointing out the need to specify the fact that multiple studies have spanned the bespoke topics. We have replaced the term "research" by "studies". (see page 5)
Methods and analysis 1. Included criteria and excluded criteria should be separated.	Inclusion and exclusion criteria are now listed separately. (see page 9)
2. Specific setting should be provided.	In accordance with the title, we now specified that patients' homes are located in a community setting. (see page 9)
3. Provide intervention content.	While we acknowledge the relevance of providing specific information on the content in intervention studies, the current study is not characterized as such and therefore the content of the intervention is of minor importance. Rather the focus is on user experience, user engagement and usability. Therefore, we waived a detailed description of the intervention.
4. The interview guide questions should be provided.	We thank the reviewer for their interest in the specific questions. We provided the themes of our semi-standardized research instruments. Considering the open-ended nature of qualitative research, the specific questions are being developed progressively and will then be published along with the study results.
5. In "standardized research instruments" part, supplement the Cronbach value and scoring method of every instrument.	Thank you for this valuable comment. We have added a short description of the scoring method as well as information on internal

	consistency measures per instrument as appropriate. (see pages 10-12)
6. In this study, the sample size of qualitative study depends on the thematic saturation. Therefore, the sample size of 20 may be not enough for qualitative study.	Thank you for your comment on the trustworthiness of the qualitative branch of our mixed-methods study. We seek to obtain a thick description of the patients experience in the use of the telecare technology "Addison". The think-aloud protocol and the semi-structured interviews on two different occasions, embedded in the quantitative methodology framework should provide an enriched insight into the phenomena of interest. We do now point out in the limitations section that we seek sufficient richness of data but do not expect to achieve a data saturation. (see page 17)
Discussion 1. The discussion section should be deepened.	Thank you for pointing out the need for a more elaborate discussion section. We have now extended the strengths and limitations sections in the discussion . (see pages 16-17)
2. Supplement the significance of the study.	As described in response to your previous comment, we have pointed out the strength of our study in the overview section.
3. Advise to supplement the challenges of this study.	We added further limitations of our study in the discussion section. (see page 17)
4. Supplement the strengths of the study.	See above.
On the whole, the paper is well-written, but if you could get a native English speaker to edit your text, it should make parts of it a bit clearer.	The manuscript is written in collaboration with American co-authors who in response to your comment once again edited the manuscript to ensure the adequacy of its linguistic aspects.

Reviewer 3, Mrs. Lieve Roets-Merken, PhD, Radboud University Nijmegen:

Comment	**Response**
Overall, this protocol is transparent and well-designed, and in line with the SPIRIT criteria. The study aims to explore the feasibility of a culturally adapted intervention, but the authors don't call it a feasibility study.	Thank you for this valuable advice on the designation of the study design. Prior to submission of this manuscript, we already considered the term "feasibility study". However, since the goal of this study is to deepen our understanding of the potential issues and challenges that will be used as the foundations for a larger randomized control study, we purposefully decided to use the term "pilot study". The sample size, recruitment strategies, and outcomes are to be determined by the results and lessons learned from this pilot study (Lancester et al.

	2004) Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract. 2004;10(2):307-12. doi: 10.1111/j..2002.384.doc.x.
The authors' choice for the UTAUT framework has as consequence that the terminology and concepts of the primary outcomes don't match with the in qualitative research more widely spread feasibility concepts and terminology. There is nothing wrong with using the UTAUT framework, but the authors should avoid an inconsistent mix: in the title, abstract and discussion, the authors stick to their three primary outcomes (experience/usability/user engagement), but in their objectives they add concepts such as feasibility and acceptability, probably taken from the more usual frameworks on feasibility? Consequently, the concepts loose transparency, with an augmented risk of bias in data analysis and interpretation. As the study will start soon, I recommend that the authors (1) stick to their three primary outcomes and (2) incorporate the knowledge and experiences of other feasibility frameworks into their data analysis. On page 13, lines 33-34, they mention that they will use deductive codes prepared from theoretical pre-considerations. I recommend to consider to adding codes here that are based on the key areas of e.g. the framework of Bowen (How we design feasibility studies 2009) which includes several key area's that `I believe may be valuable in this study, such as demand (basic criterion when aiming at self-management), acceptability and practicality.	Many thanks also for this note on the theoretical approach and the design of our study. The theoretical framework (UTAUT) has now been removed from the objectives of our study to avoid inconsistency. (see page 8) Moreover, the UTAUT model will remain as the theoretical framework to guide our research in the collection and analysis of the qualitative data. To facilitate the subsequent main study, deductive codes will now also be derived for the area of a feasibility study with reference to the framework of Bowen (2009). (see page 15) Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M. How we design feasibility studies. Am J Prev Med. 2009;36(5):452-7. doi: 10.1016/j.amepre.2009.02.002. PMID: 19362699;

Again, we thank the editor and reviewers for their support.

VERSION 2 – REVIEW

REVIEWER	Roets-Merken, Lieve Radboud University Nijmegen, Radboud Institute for Health Sciences, IQ Healthcare
REVIEW RETURNED	22-Jul-2022

GENERAL COMMENTS	This protocol fits within a careful and extensive preparation of a clinical trial. The adjustments and explanations of the authors offer the manuscript more transparency and consistency.

VERSION 2 – AUTHOR RESPONSE

Reviewer 3, Mrs. Lieve Roets-Merken, PhD, Radboud University Nijmegen:

Comment	Response
This protocol fits within a careful and extensive preparation of a clinical trial. The adjustments and explanations of the authors offer the manuscript more transparency and consistency.	Thank you very much for your feedback and your valuable comments throughout the review process.

Again, we thank the editor and reviewers for their support.