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PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Factors Influencing Smartwatch Use and Comfort with Health Data
	Sharing: A Sequential Mixed-Methods Study Protocol
AUTHORS	Goodings, Anthony; Fadahunsi, Kayode; Tarn, Derjung Mimi; Henn,
	Patrick; Shiely, Frances; O'Donoghue, John

VERSION 1 – REVIEW

REVIEWER	Anastasia-Stefania Alexopoulos
	Duke University
REVIEW RETURNED	24-Nov-2023

GENERAL COMMENTS Summary The authors present an interesting protocol paper for a mixed methods study to: a) investigate factors influencing continued use of wearable devices; and b) determine how comfortable wearables users are with sharing their data with different parties, and what factors may influence this comfort level. With the ever-increasing use of wearables and the interest in more personalized approaches to healthcare, there is a need for such studies to better understand how we arable use may be implemented in healthcare in way that is acceptable and of benefit to users. Below I have included a few major and several minor comments: Introduction - Main comment: This section can be streamlined for clarity. There is a reasonable amount of repetition of content and to help readers follow along, would recommend using subheadings here. E.g., after third paragraph of introduction, would consider subheadings that map to data that related to (and justify the need for) the two main aims, i.e., "Continued/Persistent use of wearables" and "Comfort with sharing of wearables data". - Throughout the paper, please be consistent with "smartwatch" as one word, or "smart watch" as two separate words. This fluctuates throughout the title and paper. - Please correct to "these data" throughout the paper (from "this data"), as data are plural - Recommend also referencing the expectation-confirmation model (ECM) in the first sentence it is introduced (page 2, lines 42-43). My understanding is that the ECM will only guide data collection/analysis of the "continued use of wearables" aim - If this is the case, would include the ECM under the "continued use" subheading to make this clearer. If not, please make the connection between the ECM and Aim 2 more clear. - Page 4, line 45: change "there has been", to "there have been" - Page 5, lines 12-15: run-on sentence that is hard to follow. Consider splitting into two separate sentences.

Aims and Objectives

- These are clear, however as above, I would structure the introduction so that background data clearly map to each of these aims, and in the order in which they are presented.

Research questions

- Main comment: The introduction builds towards questions 1 and 2, however research question 3 feels like it comes out of the blue. Options include: a) make this a clear third aim throughout the entire paper, OR b) roll this into research question 2. In other words, explore the perceived benefits to quality of healthcare by wearable users as one of the factors that may influence their comfort level with data-sharing... (I would do option b).

Study design

- What exactly do the authors mean when referring to a "public health specialist"? Examples of potential positions here would be helpful.

Inclusion/exclusion criteria

- Main comment: Please provide the rationale for excluding non-continuous (i.e. <6 months) wearables users from the study. If a main aim is to understand factors influencing continued use of wearables (vs. non-continuous use), it seems to me that the perspectives of those who do not use wearables continuously are just as valuable (if not more) than those individuals who have already made wearables a habit. In other words, only gathering data from continuous wearable users is likely to bias our understanding of factors influencing continuous vs. non-continuous use. From a clinical standpoint, knowing how to promote a shift from non-continuous to continuous use is more interesting (and actionable) than understanding why people who are already engaging with their wearables like to continue them.
- Main comment: The justification for age groups is not entirely clear. I understand why the authors would like to explore an older vs younger age group, but the gap between the groups (i.e. not including 33 to 45 years) is not clear; the authors mention avoiding vulnerable ages, but this age group does not clearly fall into that category.

REVIEWER	Connie M. Ulrich Univ Penn
REVIEW RETURNED	27-Dec-2023

GENERAL COMMENTS Thank you for the opportunity to review this manuscript. Privacy remains a central concern for the public and understanding privacy in the context of smartwatch use and comfort is needed research. There are several minor concerns related to the protocol. First, the authors indicate that this is a mixed methods study, but they do not indicate the type of mixed methods study design that they are using (e.g., sequential exploratory/explanatory)? Is it more a multi methods study since the authors are using both quantitative and qualitative but not mixing the data? If it is a mixed approach, it is not clear from the research questions, which aim/question reflects the mixing and then the type of analysis that will be used for the mixing of the data. The research questions are exploratory and descriptive in nature and there is no indication of this in the analysis. The authors jump to a structural equation modeling analysis without indicating basic descriptive data and correlations to assess the data. The aim for the study is 200 participants but there is no indication that a power

analysis was conducted to ascertain whether this sample was appropriate to achieve power or whether the authors were focused on SEM and the sample that was needed for this. It is also not clear why the authors chose the two different age groups t for the focus groups. They indicate that they selected these groups to "avoid interaction with vulnerable groups", but it is not clear as to why ages 34 to 44 would be considered a vulnerable group and the justification or reasoning for a 15-year age span. One might argue that those in the second group (45-60) might be more vulnerable. With regards to the focus groups and the type of analysis, how do the authors protect the privacy of each individual if the data are not being reported in the aggregate and are based on individual responses? Isn't there a possibility of reidentification? Also, are two focus groups enough to reach saturation as some authors suggest that between three-six are needed for focus group saturation. There is no indication as to how the authors will maintain rigor of the qualitative data. For the SEM analysis, why not start with a path analytic approach since the research questions are exploratory in nature?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1	
R1.1 The authors present an interesting protocol paper for a mixed methods study to: a) investigate factors influencing continued use of wearable devices; and b) determine how comfortable wearables users are with sharing their data with different parties, and what factors may influence this comfort level. With the everincreasing use of wearables and the interest in more personalized approaches to healthcare, there is a need for such studies to better understand how wearable use may be implemented in healthcare in way that is acceptable and of benefit to users.	Thank you.
R1.2 Main comment: This section can be streamlined for clarity. There is a reasonable amount of repetition of content and to help readers follow along, would recommend using subheadings here. E.g., after third paragraph of introduction, would consider subheadings that map to data that related to (and justify the need for) the two main aims, i.e., "Continued/Persistent use of wearables" and "Comfort with sharing of wearables data".	The entire manuscript has been streamlined for clarity. Repetitions have been removed and subheadings introduced to help readers follow along.
R1.3 Throughout the paper, please be consistent with "smartwatch" as one word, or "smart watch" as two separate words. This fluctuates throughout the title and paper.	Smartwatch is now used consistently throughout the paper.
R1.4 Please correct to "these data" throughout the paper (from "this data"), as data are plural	This data corrected to these data as advised.

R1.5 Recommend also referencing the expectation-confirmation model (ECM) in the first sentence it is introduced (page 2, lines 42-43). My understanding is that the ECM will only guide data collection/analysis of the "continued use of wearables" aim – If this is the case, would include the ECM under the "continued use" subheading to make this clearer. If not, please make the connection between the ECM and Aim 2 more clear.	ECM is now discussed under continued use of wearables subheading to make it clearer.	2+3
R1.6 Page 4, line 45: change "there has been", to "there have been"	Changed.	3
R1.7 Page 5, lines 12-15: run-on sentence that is hard to follow. Consider splitting into two separate sentences.	The sentence has been rephased for clarity.	5
Aims and Objectives - These are clear, however as above, I would structure the introduction so that background data clearly map to each of these aims, and in the order in which they are presented.	We have restructured the introduction so that background data clearly map to each of the aims, and in the order in which they are presented.	2+3+4
Research questions The introduction builds towards questions 1 and 2, however research question 3 feels like it comes out of the blue. Options include: a) make this a clear third aim throughout the entire paper, OR b) roll this into research question 2. In other words, explore the perceived benefits to quality of healthcare by wearable users as one of the factors that may influence their comfort level with data-sharing (I would do option b).	We have removed the third aim.	4
R1.8 Study design What exactly do the authors mean when referring to a "public health specialist"? Examples of potential positions here would be helpful.	This had been clarified as university faculty who instruct in the field of public health and Consultants in Public Health Medicine (CPHM), a physician specialist in Ireland who has completed post-graduate training in public health	5
R1.9 Inclusion/exclusion criteria Main comment: Please provide the rationale for excluding non-continuous (i.e. <6 months) wearables users from the study. If a main aim is to understand factors influencing continued use of wearables (vs. non-continuous use), it seems to me that the perspectives of those who do not	We agree that the opinions of non-continuous users are as valuable as continuous users. We have therefore removed the 6-month restriction in the eligibility criteria. We hope the results of this study will provide	6

5

use wearables continuously are just as valuable (if not more) than those individuals who have already made wearables a habit. In other words, only gathering data from continuous wearable users is likely to bias our understanding of factors influencing continuous vs. non-continuous use. From a clinical standpoint, knowing how to promote a shift from non-continuous to continuous use is more interesting (and actionable) than understanding why people who are already engaging with their wearables like to continue them.	insights on how to promote a shift from non-continuous to continuous use of smartwatches.	
R1. 10 The justification for age groups is not entirely clear. I understand why the authors would like to explore an older vs younger age group, but the gap between the groups (i.e. not including 33 to 45 years) is not clear; the authors mention avoiding vulnerable ages, but this age group does not clearly fall into that category.	We have now included the omitted age group and rephrased the sentences. The study now compares the opinion of young adult (aged 18-44) with middle aged adult (45-64). Children less than 18 years and the elderly are excluded from the study.	6
Reviewer 2		
R2.1 Thank you for the opportunity to review this manuscript. Privacy remains a central concern for the public and understanding privacy in the context of smartwatch use and comfort is needed research. There are several minor concerns related to the protocol	Thank you for your feedback	
R2.2 First, the authors indicate that this is a mixed methods study, but they do not indicate the type of mixed methods study design that they are using (e.g., sequential exploratory/explanatory)? Is it more a multi methods study since the authors are using both quantitative and qualitative but not mixing the data? If it is a mixed approach, it is not clear from the research questions, which aim/question reflects the mixing and then the type of analysis that will be used for the mixing of the data.	We clarified that the methodology is sequential mixed-methods (quantitative-qualitative) on the basis that the results of the survey guide the content of the focus group questions, which serve to clarify and explain the quantitative survey findings.	4
R2.3 The research questions are exploratory and descriptive in nature and there is no indication of this in the analysis. The authors jump to a structural equation modeling analysis without indicating basic descriptive data and correlations to assess the data.	We have provided more details in the analysis section and included basic descriptive data and correlations in addition to the structural equation modelling.	7
R2.5 The aim for the study is 200 participants but there is no indication that a power analysis was conducted to ascertain whether this sample was	Yes, the study sample was determined based on the requirement for structural	6

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appropriate to achieve power or whether the authors were focused on SEM and the sample that was needed for this. R2.6 It is also not clear why the authors chose the two different age groups t for the focus groups. They indicate that they selected these groups to "avoid interaction with vulnerable groups", but it is not clear as to why ages 34 to 44 would be considered a vulnerable group and the justification or reasoning for a 15-year age span. One might argue that those in the second group (45-60) might be more vulnerable.	equation modelling as recommended in the literature. We have now made this clear in the section. We have now included the omitted age groups (34-44) and rephrased the sentences. The study now compares the opinions of young (aged 18-44) and middle-aged adults (45-64). Children less than 18 years and the elderly are excluded from the study.	6
R2.7 With regards to the focus groups and the type of analysis, how do the authors protect the privacy of each individual if the data are not being reported in the aggregate and are based on individual responses? Isn't there a possibility of reidentification?	The transcribed data will be anonymized. No personal data which can be used to identify participants will be included in the analysis or subsequent publications. In reporting, we meticulously review content to prevent any potential reidentification, adhering to strict ethical standards. This balanced approach enables rich insights while safeguarding privacy.	7
R2.8 Also, are two focus groups enough to reach saturation as some authors suggest that between three-six are needed for focus group saturation.	We have now increased the number of focus groups to six.	7
R2.9 There is no indication as to how the authors will maintain rigor of the qualitative data.	To maintain the rigor of our qualitative analysis, we employ multiple coders who will independently analyze the data to generate codes and themes, ensuring objectivity and diversity in interpretation. To validate the identified themes, we engage in discussions with the entire investigative theme, enhancing the credibility and reliability of our findings. This information has been added to the analysis section.	7
R2.10 For the SEM analysis, why not start with a path analytic approach since the research questions are exploratory in nature?	While path analysis is a useful approach to understanding relationship between observed variables, we have chosen the SEM based on the recommendation in the ECM	7

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VERSION 2 – REVIEW

REVIEWER	Connie M. Ulrich Univ Penn
REVIEW RETURNED	20-Mar-2024

GENERAL COMMENTS	The authors have addressed my concerns.