PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Electronic Patient-Reported Outcome Measures to enable systematic follow-up in treatment and care of women diagnosed with Breast Cancer: A Feasibility Study Protocol
AUTHORS	Thestrup Hansen, Stine; Piil, Karin; Bak Hansen, Lone; Ledertoug, Karen Marie; Hølge-Hazelton, Bibi; Schmidt, Volker

VERSION 1 – REVIEW

REVIEWER	Potter, Shelley University of Bristol
REVIEW RETURNED	21-Jun-2022

GENERAL COMMENTS	This is a well-written protocol that clearly describes the proposed study. I would strongly recommend it for publication

REVIEWER	Sztankay, Monika Medical University of Innsbruck
REVIEW RETURNED	11-Aug-2022

GENERAL COMMENTS	The reviewer comments are attached as a seperate file.

VERSION 1 – AUTHOR RESPONSE

Reviewer #1

Comment	Response
1 This is a well-written protocol that clearly describes the proposed study. I would strongly recommend it for publication	1 The authors would like to thank the reviewer for the positive comment and evaluation.

Reviewer #2:

Comment	Response
1 The manuscript under review presents the feasibility study protocol for the implementation of electronic patient-reported measures for the systematic follow-up in women diagnosed with breast cancer undergoing different types of	1 The authors would like to thank the reviewer for the positive comment on the relevance of our study to BMJ Open.

	reconstructive breast cancer surgeries in the outpatient setting of a tertiary university hospital. It is a timely topic and the application of introductory/ educational material for coaching different stakeholder groups, the patient reminders for questionnaire completion and process evaluation of ePROM implementation is comprehensive. I would, nevertheless, have some comments and suggestions (please see below).		
2	**TITLE:** "Electronic Patient-Reported Outcome Measures integrated in treatment and care of women diagnosed with Breast Cancer: A Feasibility Study Protocol"; according to the abstract, ePROMs are implemented to enable systematic follow-up in breast cancer patients post-surgery. The title should reflect that.	2	We have added to the title that the implementation of ePROMs intends to enable systematic follow-up;It has therefore been revised to: *'Electronic Patient-Reported Outcome Measures to enable systematic follow-up in treatment and care of women diagnosed with Breast Cancer for systematic follow-up: A Feasibility Study Protocol'* (page 1, line 1)
3	**ABSTRACT** **Assessment time points:** Please specify. In the Abstract (p.2, line 45): "baseline, 1-year follow-up, 3-year end-point"	3	We agree that the assessment time points can be clearer and these are now specified with the information, that baseline is after diagnosis and before surgery. *'EPROMs are collected at the following assessment time points: baseline (after diagnosis, before surgery), 1-year follow-up, and 3-year end-point.* *'* (page 2, 21)
4	**Feasibility study: aria**Please specify outcomes.	4	Feasibility outcomes are now added to the abstract within the methodology section: *'Subsequently, we designed a non-controlled feasibility evaluation on the outcomes acceptability, demand, implementation, practicality and integration'* (page2, line 16)
5	**INTRODUCTION** Please define what you mean by the "proactive use of ePROMs" (page 6, line 45; page 7, line 49).	5	The term 'proactive PROMs' is defined in the introduction section on page 6 line 24 as: *'Proactively, meaning that the clinicians actively reviews the patients' PRO answers during therapy, and uses the feedback from patients to optimize the treatment and care'* (page 2, line 15)

			The authors suggest keeping this definition in the introduction section.
6	Page 6, line 47: “focussing care on individual values”: The BREAST-Q is assessing patients’ HRQOL and different aspects of satisfaction with physical appearance and care. Please specify how you will assess values.	6	Thank you for pointing out the missing link between satisfaction outcomes, HRQL outcomes and individual values. We have revised the hypothesis sentence: *‘(including dialogue on satisfaction and HRQOL outcomes), promotes mutual understanding on patients’ preferences during patient trajectories’* (page 6 line 19)
7	**METHODOLOGY** **Feasibility outcomes**: The actual outcome variables for feasibility assessment – given that this is the protocol of a feasibility study – are vaguely or not at all defined and need to be consistent throughout the manuscript.	7	Good point. We have now provided the definition on feasibility studies by Bowen et al. (2009) plus outcome variables assessed within the description of the study design. *‘In this study, the term feasibility was inspired by Bowen et al. (2009) who introduce the term feasibility study for a more broad use to encompass any sort of study that can help investigators prepare for full-scale research leading to intervention study [42]. We investigated and evaluated feasibility outcome variables including acceptability, demand, implementation, practicality and integration as described by Bowen and colleagues throughout three sub-studies (Figure 1 and Table 1) with the following aims. ’* (page 7, line 8) Finally, we have added a table 2 including an overview of feasibility outcomes (page 9, line 3).
8A	In Section “Study Design” (page 7, line 13), the authors list the following parameters: Study I: “patient’s experiences related to acceptability, practicality and demands on completion of PROMs” (page 7) Study II: “nurses’ and surgeons’ experiences related to acceptability, introduction (what do you mean by that?), practicality and proactive application of the PROM intervention” (page 7).	8A	We have replaced the word introduction with implementation aligned with the terminology presented within the variables and the feasibility terms presented by Bowen et al. (2009): *‘To investigate the nurses’ and surgeons’ experiences related to acceptability, implementation, practicality, and proactive application of the PROM-intervention in clinical practice.’* (page7, line 19) The same variables are repeated and further explained within the data collection section

8B	On the next page (p. 8, line 3), the authors state that they will gather information on activities, beliefs, preferences and proactive application"	8B	This is a specification on what user experiences the survey intends to investigate. We have specified this by adding the words user experiences, individual activities and perceived demand. *'Additionally, Study II is complemented with a local anonymous survey study with department nurses and surgeons to investigate user experiences individual activities, perceived demand, preferences, and proactive application related to the ePROM-intervention'* (Page 8, line 4)
9	In section "Data collection and measurement" (page 14, line 55), the authors list "feasibility parameters, including acceptability, proactive use of ePROMs, demand, implementation, practicality and integration". (What is the difference between implementation and integration? How different user groups perceived the implementation procedure and how they perceive final integration? Please specify terms.)	9	Thank you for pointing out this missing clarification. We have added a bracket with a specification after the terms integration and implementation to explain how the terms differs. Furthermore, we have added the reference to support the use of the terms. *'The outcomes of the multimethod study relate to feasibility parameters, including acceptability, proactive use of ePROMs, demand, implementation (degree of execution), practicality, and integration (perceived sustainability and fit with infrastructure) as described by Bowen et al. (2009) [42].*' (page 18, line 9)
10A	In section "Ethnographic studies I and II" (page 15, line 10), the authors state that "Qualitative studies I and II investigate users' interests related to using ePROMs and practical interests […]". For Study I, "Data collection includes participant observations during patient consultation" (**what will be observed? Who is the observer**?)	10A	For clarity we have added the sentence: *'The participant observations and interviews will be conducted by the first author with a focus on whether, when, how, by who, why or why not the, ePROMs are proactively used. This work calls for critical reflection and transparency on the researcher's positioning, degree of participation and ability to disregard the professional lens from one's practice discipline [45,57–59]. This will be reported with the results of the studies.'* (page 18, line 3)
10B	While for Study II, there will be an "online survey with questions developed specifically for this study to investigate perceptions (what kind of perceptions? About what specifically?) and feasibility"	10B	We have specified the meaning of perceptions: *'perceptions, defined as the way in which the intervention is regarded, understood and interpreted'* (page 18, line 10)

11	In section “Analysis” (page 16, line 54 ff.), the authors state to assess “the parameters acceptability, proactive use of ePROMs, demand, introduction, practicality, and integration”. Please clarify which feasibility outcome will be assessed in which study and how this outcome (e.g. perceptions, introduction, demand, beliefs) is defined. I would recommend adding a table on this.	11	We thank the reviewer for the suggestion and agree. We have added a table 1 named “Key areas of focus for the feasibility study inspired by Bowen et al.(2009)” (page 9, line 3). Table 1 provides an overview of the outcomes/areas of focus, clarification of terms and which feasibility outcome will be assessed in which study.
12	Is a classical feasibility outcome such as completion rate part of the parameters you assess for evaluating feasibility of ePROMs?	12	Yes, completion rate is part of study III. We have added this information to Table 1 (page 9, line 3) (and the section “*Study III - Statistical analysis” (page 20. Line 5).*
13	When will the “individual interviews with patients” (study I) take place? Please include this information in Figure 2, the time point is not indicated.	13	The authors thank the reviewer for the suggestion to provide information regarding time on interviews in Figure 2. However, this is a flow-chart for the ePROMs and not all patients will be interviewed. We have provided the information on patient interviews within the data collection section within the description of Ethnographic studies I and II: *‘The time of the observations will follow the appointment times for the consultations’* (page 17, line 26)
14	Is Study III about analysing PROM data after 1 year (as stated on page 7, line 38). This would mean PROM data from T2 (according to the information on page 14, line 24). On page 8, line 12, however, the authors write that “Quantitative study III includes the ePROM database to explore the patient population and their outcomes at T1 (i.e. baseline).” and “The evaluations (does this mean the PRO data or user evaluations?) of T2 and T3 will be reported elsewhere.” Therefore, it is not clear to me which data (from T1 or T2) will be reported in Study III. Please specify.	14	Thank you for pointing out this unclear field related to Study III. We have added to the study aim on study III that the analysis includes <u>baseline</u> data (page 7, line 21). We have specified that the data included for the Quantitative study III are PROMs from T1, patients’ baseline PROMs (page 8, line 22) We have specified: ‘*PROM data from T2 and T3 will be reported elsewhere’* (page 8, line 24).
15	**Exclusion criteria (page 8, line 52):** Please add the rational for excluding women treated with letrozole aromatase inhibitor endocrine therapy as primary treatment. Why are other substances of adjuvant endocrine treatment not excluded?	15	We have added information to the exclusion criteria that letrozol as primary treatment is a nonsurgical regime: ‘*nonsurgical regime, therefore outcome measures of satisfaction with surgical result is not relevant’* (page 10, line 14).

16	I do not get the meaning of the following sentence (page 9, line 28): “Recruited nurses and surgeons will follow the patient participants, as nurse and surgeon participants are those whom the patients met (will have met?) throughout their visit on the day of observation by the present researcher.” Is this about treatment continuity? Will patients be met by the same nurse and/ or surgeon participant at every visit – or how will they “follow” the patient?	16	We have revised the sentence to clarify the intended meaning: ‘*Nurses and surgeons included for the qualitative studies are those whom the patients met throughout their visit on the day of observation by the present researcher’* (page 11, line 5).
17	**Strategies for the introduction of ePROMs (page 10, line 45 ff.):** “This study acknowledges the introduction of ePROMs as a dissemination process […]”. The introduction of ePRO is a complex intervention according to the MRC guidelines. It does not become clear what the authors are heading at. Coaching stakeholders for the use of ePROMs is already part of the intervention, given the authors aim to assess proactive use etc. which will be influenced by a priori coaching. This paragraph is obsolete and causes more confusion – for an audience familiar with the differential definitions of dissemination and implementation – than necessary. I suggest focussing on presenting the strategies for introducing the ePROM intervention to the stakeholders.	17	Thank you the suggestion to delete the explanation on the dissemination and implementation terms. We have deleted this to decrease redundancy (page 12, line 13).
18	**Education programs:** “how to proactively engage in ePROMs with patients” (page 12, line 31): what do you mean by engaging IN ePROMs? In the discussion of PRO data with patients?	18	We have revised the sentence accordingly to: *‘objectives, processes, and rationales, including how to objectives and processes ,proactively engage with ePROMS with patients’* (page 14, line 9)
19A	What is the difference between the 4-hours training for nurses and the 1-hour training for surgeons?	19	To clarify the difference between the lengths of nurses and surgeons training sessions, we have added the following information: *“Nurses were expected to be the main users of PROM-data for psychosocial support and conversations with patients on e.g. body image. Therefore nurses training was planned to be more comprehensive*

			than surgeons' training including skills training" (Page 13, line 25)
19B	How do you provide the monthly 1-hour trainings for nurses? (page 12, line 34).	19B	We have specified that the 1-hour trainings are characterized as internal educational sessions: *'The intervention is associated with continuous, monthly, 1-hour internal educational sessions that address issues related to the proactive use of ePROMs in clinical practice to improve outpatient nurses' knowledge and skills in relevant issues such as body image-related distress '* (page 14, line 11)
20	Since I do not see this listed in the education content for surgeons, why is this group not coached in how to proactively engage with ePROMS with patients (compared to nurses)?	20	The surgeons were taught about the rationale of proactively engagement with ePROMs. We have added this information: *'aiming to inform about its objectives, processes rationales including how to proactively engage with ePROMS with patients'* (page 14, line 21)
21	**Table 1.** Why is the **pre**operative version of the BREAST-Q: Physical Well-Being Chest assessed at **T2** (see page 13, Table 1).	21	We believe that the table may have been difficult to read because of the missing frames. These are now provided (page 15, line 6) If we understand the reviewer correctly, the reviewer ask why there is only a preoperative version of the "Satisfaction with breasts" questionnaire, although it is assessed in T2. This is an error from our side. Thank you for seeing this. We have corrected the Table 2 and specified that the "Satisfaction with Breasts" is for pre- and postoperative measures. (Table 2. Study assessment times, measures and tasks).
22	**Intervention with ePROMs** Baseline (T1) is defined as "prior to patients 4-day postsurgical control with nurse" (page 14, line 22). According to Figure 2, patients are completing Baseline/ T1 before surgery. Please specify in the text (page 14) that the baseline assessment (prior to patients' 4-day postsurgical control) takes place before surgery.	22	We have provided information that T1 is completed by patients before surgery. *'T1, baseline data completed before surgery'* (page 16, line 12)

23 Please add the rational for using PRO data assessed BEFORE the surgery in the post-surgical follow-up assessment (and not assessing PROMs after surgery to use in the post-surgery consultation).	23 We have added the rational for using PROM data assessed BEFORE the surgery: '*The rational for using baseline PROMs completed before surgery for the 4-day postsurgical is: 1) The patient's assessment of breasts before the surgery is recommended to be actively discussed with the patient in relation to the choice of breast prosthesis, bra and life with a changed body after breast cancer, 2) The baseline measurement is essential to monitor patients' satisfaction with breasts over time and surgical results are best evaluated at the earliest one year after surgery.* (Page 16, line 14)
24A This paragraph (page 14, line 5 ff.) does not include the information that the timing for T2 differs between "treatment arms" (i.e. surgical therapy up-front vs. surgical therapy after neoadjuvant treatment).	24A We have added the information on the two study arms. *'The patients receive two to three questionnaires, depending on their trajectory, over a 3-year period, with treatment arms surgical therapy up-front or neoadjuvant therapy before surgical therapy'* (page 16, line 7)
24B The "1-year follow-up" (page 14, line 24) for T2 does not add up (according to Figure 2, it is 11 or 18 months). Please add this information for clarity.	24B The authors have added information to the sentence that T2 is assessed 11 or 18 months after surgery dependent on treatment regime as shown in Figure 2. *'second, for the 1-year follow-up (T2, follow-up completed 11 or 18 months after surgery dependant on treatment regime), which is initially a nurse consultation '* (page 16, line 12)
25 Also please add time point to description of T3 (page 14, line 47): "Patients who accept correction or reconstruction of the breasts after their 1-year follow-up receive a third ePROM (T3).", meaning 12 months after correction/ reconstruction.	25 We have provided information that the T3 and endpoint is sent to patients 18 months after T2. *'Patients who accept correction or reconstruction of the breasts after their 1-year follow-up, the T2, receive a third ePROM 18 months after T2, as patients are expected to have finished their breast surgical trajectory at this point (T3, endpoint)'* (page 17, line)

26	Typo on page 14, line 22: patients' 4-day postsurgical control	26	The typo is corrected.
27	**Figure 2:** Please check for typos, there are a few, e.g. "Patients are invited througH digital …" etc.	27	We have closely revised and corrected the figure 2 again, and hope it now reads well without typos
28	**Data collection and measurements** Ethnographic studies I and II The outcomes for these sub-studies are not clear and not uniformly reported throughout the manuscript.	28	We have provided the Table 1 with information on key areas of focus for the feasibility study plus specification on which studies that investigates which outcomes. (page 9, line 3) Furthermore, we have provided more information on the Interpretive Description methodology within the study design section for the reader to better understand the rationales of the qualitative studies: '*Qualitative studies are guided by interpretive description (ID), an inductive methodology developed to explore clinical problems with the objective of generating insights that inform clinical practice [45]. ID draws upon recognised qualitative research techniques from ethnography, naturalistic inquiry, grounded theory and phenomenology but focuses on explicit research logic and flexibility, permitting researchers to apply and combine the necessary pragmatic strategies to answer the research question [46]. The composition of an ID study is guided by distinctive features, including: scaffolding the study, framing the study, strategizing a credible study, entering the field, constructing data, making sense of data, and conceptualizing findings[46]. The result is a coherent, conceptual description containing understandings and illuminations of clinical phenomena, characteristics, patterns and structures in order to develop practice. The ID methodology will support understanding and knowledge related to the study feasibility outcomes.*' (page 8, line 8)
29	How will you operationalise "demand, introduction, practicality and integration (page 16, line 57 ff)	29	We have added a sentence to explain how the terms are operationalized within the analysis: *"These outcomes will be informed and further analysed from the observation and interview data that is expected to add rigour*

			information on priorities, mechanisms and practicalities in the outpatient clinic to answer the study aims".(Page 20, line 3)
30	Observations: what will be observed?	30	We have added following information to the *Ethnographic studies I and II* section: *'*The participant observations and interviews will be conducted by the first author with a focus on whether, when, how, by who, why or why not the, ePROMs are proactively used. This work calls for critical reflection and transparency on the researcher's positioning, degree of participation and ability to disregard the professional lens from one's practice discipline [45,57–59]. This will be reported with the results of the studies. (Page 17, line 3)
31	Page 15, line 24: Add "For study I, data collection includes […]" and "For study II, the survey with nurses and surgeons […]." (page 15, line 36).	31	Thank you for your suggestions, we have adapted these accordingly: *'For study I and II, data collection includes participant observations during patient consultations with nurses and surgeons and individual interviews with patients…..'* (page 17, line 23)
32	How do you define "perceptions"? (page 15, line 40)	32	We have added a definition of the term perceptions after the term: *'perceptions, defined as the way in which the intervention is regarded, understood and interpreted'* (page 18x, line 10)
33A	**Analysis** Page 16, line 52: It is not clear how qualitative data (from the observations, interviews and the survey) will be analysed. The phrase: "The analysis will be inspired by the theoretical framework of person-centred care to evaluate the feasibility of the ePROM intervention, […]." is not comprehensive.	33A	We have added information on how data is analyzed guided by the ID methodology: *'ID does not prescribe a straight forward data analysis process but relies on the pragmatic obligation for the researchers to work data beyond initial descriptive claims towards interpretations that will enlighten the phenomenon investigated in a new and meaningful manner [68].The ID analysis aims to make sense of what has been observed and heard through an explorative process where questions are continuously posed to the data and answers are sought to generate explanations supported by theory '* (page 19, line 16)

33B How will a “framework or person-centred care” allow for the evaluation of the feasibility of an ePROM intervention (which has very pragmatic features)? This paragraph needs to be essentially revised.	33B We have revised the sentence to support coherence and clarity on the planned analytical process: *‘The analysis for study I and II will be inspired by the theoretical framework of person-centred care to evaluate the feasibility of the proactive ePROM intervention by questioning if the ePROM intervention supports the intentions on targeted, individual, psychosocial support and assessment of candidates for reconstructive and/or corrective breast surgical therapy’* (page 19, line 22)