PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The iPROMOS Protocol: A Stepped-Wedge Study to Implement Routine Patient Reported Outcomes in a Medical Oncology Outpatient Setting
AUTHORS	Roberts, Natasha; Mudge, Alison; Alexander, Kim; Wyld, David; Janda, Monika

VERSION 1 – REVIEW

REVIEWER	Reviewer name: Michelle M Holmes Institution and Country: AECC University College, U.K. Competing interests: None declared.
REVIEW RETURNED	12-Nov-2018

GENERAL COMMENTS	This study is very interesting and relevant. From a methodological point of view, this study is sound and follows appropriate guidance. Very minor points for improvement: 1) Within the introduction or discussion there is no mention of Kotronoulas et al., (2014) systematic review on the value of PROMs in cancer care. This paper may be of value. (Kotronoulas, G., Kearney, N., Maguire, R., Harrow, A., Di Domenico, D., Croy, S., & MacGillivray, S. (2014). What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials. Journal of Clinical Oncology, 32(14), 1480-1501. doi: 10.1200/jco.2013.53.5948) 2) Please note if the PRO-CTCAE has been validated, and the reliability of the PROM. 3) Is there any evidence that the PRO-CTCAE is acceptable to patients? 4) Please include further details on the staff survey, how is staff knowledge being measured? 5) Please summarise Berry et al., (2014) and why this was used for the sample size, and how it compares to the planned study. 6) Please provide a short summary of the Miles and Huberman (2014) approach to content analysis. Overall, this was a great study protocol and I am looking forward to reading the results. It was particularly great to see the details regarding the pre-implementation information and how this informed implementation design.

REVIEWER	Reviewer name: Jonathan Field
	Institution and Country: Independent Practice, UK
	Competing interests: None
REVIEW RETURNED	19-Nov-2018

GENERAL COMMENTS	I thank the authors for their description of this study. Implementation of PROMs into complex clinical environments is proving challenging and understanding drivers and barriers better is important.
	The rational and methodology described is comprehensive and appropriate for the study aims. Potential issues through use of a single facilitator who will also be responsible for some data collection are addressed in the paper

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Michelle M Holmes

Thank you for your helpful comments, please see the responses below.

1) Within the introduction or discussion there is no mention of Kotronoulas et al., (2014) systematic review on the value of PROMs in cancer care. This paper may be of value. (Kotronoulas, G., Kearney, N., Maguire, R., Harrow, A., Di Domenico, D., Croy, S., & MacGillivray, S. (2014). What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials. Journal of Clinical Oncology, 32(14), 1480-1501. doi: 10.1200/jco.2013.53.5948)

Thank you for pointing out the additional findings of Kotronoulas et al (2014), these have been included on page 6, lines 110-113:

"Several studies have shown that using PROMS in routine care leads to improved quality of life (QOL) [3, 5] as well as improved communication, decision-making, care planning and patient satisfaction [6-9]."

2) Please note if the PRO-CTCAE has been validated, and the reliability of the PROM.

This has been added as a footnote at the bottom of page 12, corresponding to line 201:

"5 PRO-CTCAE is a validated (119 of 124 items met at least 1 construct validity criterion) symptom-reporting PROM that has been demonstrated to be reliable (test-retest reliability was 0.7 or greater for 36 of 49 pre-specified items) and responsive (item changes corresponded to the QLQ-C30 scale) [27]"

3) Is there any evidence that the PRO-CTCAE is acceptable to patients?

There is evidence that PRO-CTCAE is acceptable to patients. This has been added to the footnote on page 11, corresponding to line 203:

"There are a number of studies that have demonstrated that the PRO-CTCAE is acceptable to patients from differing cancer populations internationally [28,29]"

4) Please include further details on the staff survey, how is staff knowledge being measured?

The survey allowed staff to rate their own knowledge on 5 questions scored on a Likert scale, for example, "My understanding of PROs is… (very poor, poor, fair, good, very good), "In terms of interpreting PROs my skills are…(very poor, poor, fair, good, very good)", "My lack of understanding of PROs is barrier to using them in clinical practice (almost never, rarely, sometimes, often, almost always).

Information about the survey has been included as a footnote on p:10:

"The staff survey was modelled on Rouette's (2015) assessing knowledge and perceptions about PROMs, including barriers and facilitators [26]"

5) Please summarise Berry et al., (2014) and why this was used for the sample size, and how it compares to the planned study.

This has been included in lines 320-325, p20:

"Berry et al (2014) conducted an RCT which compared symptom reports between clinics using an electronic reporting tool. They assessed both processes and outcomes of care, comparing the impact of PROM reports between the control and intervention clinics. It was used to guide the sample size calculations because this study measured the identification of symptoms in usual care versus a symptom-PROMs intervention."

6) Please provide a short summary of the Miles and Huberman (2014) approach to content analysis.

A brief summary has been included on lines 350-353, p21

"who propose an analysis of systematic coding, word by word, presenting the data visually to identify patterns."

Overall, this was a great study protocol and I am looking forward to reading the results. It was particularly great to see the details regarding the pre-implementation information and how this informed implementation design.

Reviewer: 2

Reviewer Name: Jonathan Field

Institution and Country: Independent Practice, UK

Please state any competing interests or state 'None declared': None

Please leave your comments for the authors below I thank the authors for their description of this study. Implementation of PROMs into complex clinical environments is proving challenging and understanding drivers and barriers better is important.

The rational and methodology described is comprehensive and appropriate for the study aims. Potential issues through use of a single facilitator who will also be responsible for some data collection are addressed in the paper

Thank you very much for time to review this protocol