PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Is it possible to predict improved diabetes outcomes following Diabetes Self-Management Education: a mixed methods longitudinal design
AUTHORS	Huxley, Caroline; Sturt, Jackie; Dale, Jeremy; Walker, Rosie; Caramlau, Isabela; O'Hare, Paul; Griffiths, Frances

VERSION 1 - REVIEW

REVIEWER	Cradock, Sue University of Leicester
REVIEW RETURNED	07-Jul-2015

GENERAL COMMENTS	This is a novel study looking at ability of health care professionals to predict the outcomes of participants who undertake diabetes self management education. It highlights the challenges faced by HCPs when being asked to make predictions in relation to outcomes they have little control over, as well as the potential impact of complex interventions such as DSME programmes. The procedures described in the paper appear to include items from the overall study rather than specific to this study? Or this may be the way they are described. Please could you specify what data was collected and when? Some of the data collected to support the validity of the HCP predictions appear to be self report data? Please comment on how this may affect the actual outcomes. Did you have a pre determined % accuracy of HCP prediction? Can you discuss what would would expect the level of prediction should be? I am not sure how the inclusion of what HCPs say about participants diet ("discussion took place about his probable eating habits without any available data regarding this") adds to the conclusions without having analysed the relationship overall of assumptions made by HCPs and their relationship to predictions. Did you consider asking participants to predict what outcomes they expected? Would be interesting to see how they compared (another study perhaps). I think your study raises issues for training HCPs? Lastly..you talk about DSME/structured education and education as if they are the same thing..could you please define what you mean by each?

REVIEWER	Gosling, Charles Lewisham and Greenwich NHS Trust
REVIEW RETURNED	10-Jul-2015

GENERAL COMMENTS	This is a useful and very important piece of work. Structured education is an evidence based and essential component of diabetes care. To date, as identified by the authors, only a small proportion of those with Type 2 diabetes are offered access to a structured education programme and even fewer attend. The research question would appear to identify if there is a means of establishing who is likely to benefit from Diabetes Self-Management Education. If established such information would be of great value in identifying those for whom maximum effort could be used to increase likelihood of attendance. This would be of huge benefit to commissioners of health and providers alike. The negative findings are also of importance in that DSME should be promoted to all people with diabetes - also with significant implications for commissioners and providers. The methodology used in this trial is of necessity research based, with use of relatively time consuming measurements (PAID, RDKS, DMSES and HADS). Such an intervention would not be practical at scale. If the study had demonstrated a strong ability to identify prediction of benefit from DSME, a more concise tool would need to be developed to allow the intervention to be delivered at to the wider population. Primary health care professionals, especially practice nurses, have extensive prior knowledge of their clientele. It might be useful to know if this 'soft' prior knowledge is a useful indicator in assessing likelihood of benefit from DSME. This might be an area for future work. Suggested minor revision - reference change p16 DSME has been shown to have an effect on HbA1c, and this is a key clinical marker of disease control (ref 6,7). Should this not read ref 5,6 as Deakin did show reduction in HbA1c whereas Davies et al did not.

REVIEWER	Brokaw, Sarah Montana Diabetes Program, Department of Public Health and Human Services
REVIEW RETURNED	16-Jul-2015

GENERAL COMMENTS	4) Yes, the methods could be repeated, but it wasn't clear to me how the 19-item RDKS with 0 or 1 point per item could have a summed score between 0 and 23. However, this scale is cited if another researcher were to use this scale. 11) While the study employed practice nurses as the DMFs, physicians' clinical experience is discussed in the comparison with wider literature section. The experience of nurses in this study may not be generalizable to other clinicians such as physicians. This should be clarified in this section or the conclusions section, possibly stating that more research should be conducted on other types of clinicians. 12) The study limitations should reference the relatively small number of patients (n=30 at baseline, n=27 at follow-up) in the study to draw these conclusions. 15) Check for consistent capitalization of words. (i.e., the title

	practice nurses; the first letter of the variables in the outcome variables and results sections of the abstract; type 2 diabetes; some journal titles in the references). Check for use of acronyms after first reference. (i.e., Diabetes Self-Management Education (DSME); healthcare professionals (HCPs) is first written without an acronym). Use of either abbreviations or full names in journal titles in the references, according to BMJ guidelines. Space is needed between "assessthe" in the introduction, "consultationstook" in the procedures, "Healthprofessionals" in summary, "type 2diabetes" in references, "particularlytype" in Table 1. Suggest rewording "...HCPs that they know who to offer DSME to." as "HCPs that they know whom to offer DSME." Table 3 - suggest adding N to the baseline and to the follow-up. Table 4 - unsure what "12/? 27" means in the second column, fourth row.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

The procedures described in the paper appear to include items from the overall study rather than specific to this study? Or this may be the way they are described. Please could you specify what data was collected and when?
Response: A clarifying sentence has been added to the end of the Procedures section and another deleted from the Outcomes assessments framework to avoid duplication.

Some of the data collected to support the validity of the HCP predictions appear to be self report data? Please comment on how this may affect the actual outcomes
Response: The self-report data was demographic (age, ethnicity, gender) and psychosocial (diabetes distress, anxiety, depression, self-efficacy and knowledge) and it is possible that completing these outcome assessments at baseline were interventional in their own respects. We have added a sentence to this effect in the Study limitations section.

Did you have a pre determined % accuracy of HCP prediction? Can you discuss what would would expect the level of prediction should be?
Response: We have added a statement at the beginning of the Outcome assessment framework section to make our a priori assumptions explicit and justify them. In doing this we have added another reference no 22 Alam et al 2008.

I am not sure how the inclusion of what HCPs say about participants diet ("discussion took place about his probable eating habits without any available data regarding this") adds to the conclusions without having analysed the relationship overall of assumptions made by HCPs and their relationship to predictions.
Response: This statement was made in the Results section although we acknowledge that this is the only reference to the audio-recorded group assessment discussion data and have therefore removed this sentence because we are not reporting a comprehensive analysis of this data.

Did you consider asking participants to predict what outcomes they expected? Would be interesting to see how they compared (another study perhaps).
Response: We did not ask participants to do this and have clarified this in Outcome assessment framework section.

I think your study raises issues for training HCPs?
Response: We have included a statement to this effect in the section Comparison with the wider literature.

Lastly, you talk about DSME/structured education and education as if they are the same thing. Could you please define what you mean by each?
Response: We have predominantly used the term DSME because we recognise that BMJ Open is an international journal and Structured Education is a UK term. Broadly speaking we believe that in contemporary international literature they are the same thing. We have amended our language to be consistent in our use of DSME throughout the paper and added a sentence to contextualise our first use of the term Structured Education in the Introduction section.

Reviewer 2
Primary health care professionals, especially practice nurses, have extensive prior knowledge of their clientele. It might be useful to know if this 'soft' prior knowledge is a useful indicator in assessing likelihood of benefit from DSME. This might be an area for future work.
Response: We agree that this is a useful further research question. We feel that we have commented on this sufficiently already in the Strengths and limitations section when we write "In consultations, health professionals often have prior knowledge of their patients and draw on non-verbal data to make their assessments"

Suggested minor revision - reference change p16 DSME has been shown to have an effect on HbA1c, and this is a key clinical marker of disease control (ref 6,7). Should this not read ref 5,6 as Deakin did show reduction in HbA1c whereas Davies et al did not.
Response: Thank you for spotting this referencing typo and we have revised this in table 1.

The methodology used in this trial is of necessity research based, with use of relatively time consuming measurements (PAID, RDKS, DMSES and HADS). Such an intervention would not be practical at scale. If the study had demonstrated a strong ability to identify prediction of benefit from DSME, a more concise tool would need to be developed to allow the intervention to be delivered at to the wider population.
Response: We assume this comment arises from our final sentence in the Outcomes framework analysis "All data in the framework could be available to nurses during routine consultations if they chose to access the information". Whilst in this study we employed research instruments to formally assess these outcomes, the research team consists of 5 clinicians who affirm that a clinician can make an assessment of a patient's mood, distress, knowledge and confidence in a routine clinical encounter without the use of research instruments. In a real world assessment it may have been these clinical assessments which would have formed the basis for making DSME outcome predictions. Given that we did not find that predictions are reliable we believe that we do not need to consider this further.

Reviewer 3
The methods could be repeated, but it wasn't clear to me how the 19-item RDKS with 0 or 1 point per item could have a summed score between 0 and 23. However, this scale is cited if another researcher were to use this scale.
Response: Thank you for pointing out this error. We have now corrected the error in Table 1.

While the study employed practice nurses as the DMFs, physicians' clinical experience is discussed in the comparison with wider literature section. The experience of nurses in this study may not be generalizable to other clinicians such as physicians. This should be clarified in this section or the conclusions section, possibly stating that more research should be conducted on other types of

clinicians
Responses: We have added a sentence in Comparison with wider literature section to point out that the findings may be different across different clinical professions.

The study limitations should reference the relatively small number of patients (n=30 at baseline, n=27 at follow-up) in the study to draw these conclusions.
Response: We have amended two sentences in the Conclusion section and the Abstract to remind readers of the small sample size and the size of the data set available to nurses to make decisions.

Check for consistent capitalization of words. (i.e., the title practice nurses; the first letter of the variables in the outcome variables and results sections of the abstract; type 2 diabetes; some journal titles in the references).
Response: Checked and corrected

Check for use of acronyms after first reference. (i.e., Diabetes Self-Management Education (DSME); healthcare professionals (HCPs) is first written without an acronym).
Response: Checked and corrected

Use of either abbreviations or full names in journal titles in the references, according to BMJ guidelines.
Response: Checked and corrected

Space is needed between "assessthe" in the introduction, " consultationstook" in the procedures, "Healthprofessionals" in summary, "type 2diabetes" in references, "particularlytype" in Table 1.
Response: Checked and corrected

Suggest rewording "...HCPs that they know who to offer DSME to." as "HCPs that they know whom to offer DSME."
Response: Revised according to this suggestion.

Table 3 - suggest adding N to the baseline and to the follow-up.
Response: N has been added as suggested.

Table 4 - unsure what "12/? 27" means in the second column, fourth row.
Response: The /? 27 was left in by mistake in a communication between co-authors. It has now been removed. We have added a footnote to this data description on the 4th row to aid interpretation of the data.

Editor's comments
1/ The conclusions should be toned down - this is a small study with no sample size calculation (specific to this research question)
Response: Two sentences have been amended to remind the reader about the small sample size in the conclusions at the end of the manuscript. We have amended the abstract for the same purpose. Our only recommendation for practice is that clinicians should offer DSME according to national/international guidelines. As this is a conclusion supporting current UK health policy we feel it is appropriate to retain it.