Author's response to reviews

Title: Identification of behaviour change components in swallowing interventions for head and neck cancer patients: Protocol for a systematic review

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Version: 2
Date: 13 May 2015

Author's response to reviews: see over
Dear Editors and Reviewer

Thank you for your feedback and comments on our manuscript. We have made some modifications to the manuscript and our responses are listed below.

Reviewer 1

**Overall:**

*Generally, this protocol is not clearly operationalised and the design lacks a clarity of purpose. There is an absence of any stated hypothesis.*

*The authors' stated aim (pp 6) is to, 'identify the behaviour change strategies that HAVE BEEN USED in swallowing intervention programmes' - which differs from their title, stated as to identify the, 'components of behavioural interventions AIMED AT IMPROVING swallowing outcomes IN HEAD AND NECK CANCER PATIENTS.'*

Our Response

Thank you for alerting us to this mismatch of title and aim. We have modified our title to better reflect the aim: Identification of behaviour change components in swallowing interventions for head and neck cancer patients: A protocol for a systematic review. We have also modified and/or added to the manuscript in the abstract and introductory sections (pages 6-7) to clarify the purpose of the review. In the abstract we now specify,

‘This systematic review will use a behavioural science lens to examine the content of previous interventions in this field. It aims to identify (a) which behaviour change components are present, and (b) the frequency with which they occur in interventions deemed to be effective and non effective.’

On page 6, we have added

‘Behaviour change cannot be assumed; many behaviour change interventions may fail, not because the intervention is ineffective in modifying the clinical outcome, but because the individual fails to adhere to the recommended advice. This phenomenon has been recognised in the swallowing rehabilitation literature; a previous retrospective study of 497 patients, reported a statistically significant difference in functional swallowing status (return to full oral diet) in patients who adhered to their exercises compared with those who did not [14].’

On page 7, we have added

‘This review examines the behaviour change components that have been reported in previous swallowing intervention studies with the view to informing the development of new interventions in this field. A clear description of these components will be useful in transparently describing the content of this complex intervention. Specifying intervention content in a consistent way is desirable for replication of effective interventions, and avoiding replication of ineffective interventions. This in turn enhances the ability of the field to accrue evidence that will allow greater confidence in answering questions about what works. It is unlikely at this stage, that we will be able to be conclusive about which
behavioural components are most effective, but we can map how frequently they occur in interventions reported to be effective or non effective. ‘

Our Response to overall comment:

As indicated in the manuscript, we have followed the PRISMA P guidelines (2015) to ‘operationalise’ the steps in this review. We have been systematic in our planned approach to searching, screening and selecting appropriate studies to include in our review. We also have a focused question with a systematic plan for analysis: Which behaviour change components are reported in swallowing interventions for head and neck cancer patients, and how frequently do they occur in interventions deemed to be effective? (p6) Other published systematic reviews (such as Dombrowski et al 2012 - reference 18 in our manuscript) have used earlier versions of the validated behaviour change tools we plan to use. While we agree that hypothesis testing is important, we also believe it need not be the only focus of a systematic review. A recent publication by Petticrew (2015) provides a useful summary of the changing landscape of systematic reviewing which highlights the importance of systematic reviews that offer an alternative to the emphasis on summarizing effect sizes. As articulated in this paper, the goal of systematic reviews of complex interventions should be to answer a broader question: ‘What has happened previously when this intervention has been implemented across a range of contexts, populations and subpopulations, and how have those effects come about?’ Our review focuses on characterizing ‘how effects have come about’, by describing the ‘ingredients’ of swallowing interventions, and how ingredients differ across effective and non-effective interventions.

We recognize that the literature related to swallowing interventions in head and neck cancer does not represent a mature research field with a large number of randomised trials. To our knowledge, the field has not previously identified and described the potential impact that behaviour change factors may have on intervention outcomes in any systematic way. We see this review as a starting point. A review like ours may aid design of future interventions by a) identifying which intervention components have been used with some success in the past, and b) by so doing, encouraging intervention designers in this field to recognize and adopt a behavioural science perspective on their swallowing interventions, and its standardised terminology. As more high quality studies are generated, and the various components of these complex interventions are mapped out, it may in time become more feasible to perform hypothesis testing and meta-analysis. We have inserted a paragraph at the end of the manuscript to summarise this perspective.

We provide a link to the Petticrew (2015) paper, as we feel it is outside the scope of this response letter to go into further detail about the core nature of systematic reviews.

Link to Petticrew (2015)

http://www.systematicreviewsjournal.com/content/pdf/s13643-015-0027-1.pdf

Background:

Dysphagia after curative surgery and after curative chemo-radiotherapy should be separately described, as these treatment pathways and swallowing outcomes are quite different, whereas in ‘background’ section these have been conjoined.
In their proposal, the authors refer to 'behaviour change' and to a number of theories, narrative analysis etc., but the outcome as stated (from the title) is swallowing function - so it is not at all clear how they will get from a to z. Also, the term 'behavioural change' is not patient-focused language.

Our Response

We agree that swallowing outcomes may be different in patients who undergo surgery vs radiation therapy. However, in this review, we are not seeking to evaluate swallowing outcomes as they relate to different modalities of treatment. We are interested in the behaviour change strategies that are used during swallowing interventions regardless of the primary mode of cancer treatment, and how these strategies may relate to reported effect of the intervention as measured by change in the stated swallowing outcomes. We apologise if this was not sufficiently clear.

We hope that our response to the ‘overall comment’ has helped clarify our position. We plan to identify the behaviour change strategies and observe how frequently they occur in interventions deemed to be effective in modifying swallowing outcomes (with effectiveness judged according to whether statistically significant vs non significant). We recognise that mapping behaviour change strategies on to swallowing outcomes is potentially problematic, in that it assumes that behaviour change is necessary and sufficient to bring about changes in swallowing outcomes. However, to our knowledge, behavioural outcomes (i.e. adherence to swallowing exercises) are not directly measured in trials in this field. To the extent that uptake of these interventions can modify swallowing outcomes, swallowing outcomes provide the best available proxy indicator of successful behaviour change. We have now included a draft template for a Table that we may use to summarise our findings (will be added as supplementary information as the layout may change in the results paper).

Methodology:

The following registries for ongoing clinical trials are missing form their search strategy;

- Clinical Trial.gov
- MetaRegistry of Clinical Trials
- WHO International Clinical Trials Registry Platform
- Australia New Zealand Clinical Trials Registry

As the authors have decided (a priori) which tools they will use to classify the behaviours (which reads as only tools designed by staff at their centre) the proposal is not strictly systematic, nor is it at all free from bias.

Frankly, I fail to see how a 'systematic review' can be undertaken on this topic in the way proposed. It would be preferable for the authors to undertake a narrative review and then list and then classify interventions according to their proposed schema.

Our response

We have added the WHO and Australia, NZ clinical trials registries to our search strategy.
The tools that we use (behaviour change technique taxonomy, behaviour change wheel, Theory coding scheme) are all referenced in the manuscript and as stated earlier and referenced in the manuscript, have been used in other published work. They have been developed through rigorous processes including international Delphi consensus methods and have substantial work outside our institution attached to them. None of the present authors were authors on any of the papers that set out these tools, nor are any of the authors based in the same centre at UCL. We therefore do not believe that use of these tools provides a bias threat to the review. There is also not a wide selection of tools available for this specific purpose, and certainly none with this level of supporting literature.

We hope that our earlier response to the overall comment sets out our position on this systematic review. Furthermore, we once again would like to make reference to the recent publication by Petticrew (2015), which provides a timely discussion of different approaches to the “traditional” systematic review.

Although the authors make reference to one published Cochrane protocol (ref 16) on this topic, they do not make any statement about what their proposal will add that will be an addition and/or an improvement.

Knowing the literature, there will be very few papers that can be categorised in the way they propose. The interventions used with HN cancer patients are generally poorly described and most authors will not have any overtly stated, ‘theory’ to underpin them (which does not mean it does not exist!).

A classification system such as Logemann’s might be more applicable for describing and grouping the treatment of dysphagia in HN cancer patients.

Our Response

We have now added the following to the manuscript on page 6:

‘Based on their published protocol [16], we expect to examine a similar body of evidence to Perry et al. Whilst Perry et al’s review has the specific purpose of examining direct swallowing exercises (eg type, dose, frequency) in randomised trials using Cochrane methodology, our review will look more broadly at clinical trials (randomised and non randomised) with a focus on the behavioural techniques used in these interventions. We believe that these reviews will complement each other offering a broader and more balanced picture of the current evidence in this field.’

We agree that interventions may be poorly described, but as we state in our concluding remarks: ‘the findings could be useful in promoting better reporting of future studies’. Better specified interventions are more easily replicated. Furthermore, that these behaviour change interventions are not adequately reported, nor are they constructed with any explicit reference to named behaviour change theories, would be an important finding in itself. That said, from our preliminary searches we expect that we will most likely have a reasonable number of studies to be able to identify behaviour change strategies, even if not explicit theories.
We agree that most interventions have some implicit behaviour change theory. By giving patients an intervention they will adhere to it. But interventions based on theory have been found to be more effective in some domains. Interventions that have a theory base that has not been made explicit (implicit theory) should still be examined to elucidate the theoretical pathways through which they have effects on behaviour/swallowing, so that future interventions can use those same pathways.

We are unaware of any similar classification system (behaviour change wheel/taxonomy) developed by Logemann.

Writing style:

Generally the writing style is dense and a paper from 2009 is not 'recent' (ref 3, pp 4) in this field as HN cancer treatments have altered over the 6 years since, with the widespread use of Intensity Modulated Radiotherapy Treatment (IMRT) for curative treatment of large HN tumours.

Our Response

Thank you for pointing out this inconsistency – the statement refers in fact to reference 4, a review from 2013. We have now corrected this referencing error that occurred during a version change and removed the word ‘recent’

We have used the PRISMA guidelines and general journal format in writing our manuscript.

As pointed out earlier, the modality of cancer treatment is not a key focus of this review.

Editor’s Comments

In particular, it may be necessary to more clearly disentangle for the reader what appear to be two related but separate objectives within the proposed review: (1) the classification (and theoretical justification) of intervention components reported in the published literature, and (2) the relative contribution of these components to the effects observed in the evaluative evidence. Much of the emphasis in the text is on (1), but the decision to include only comparative evaluations suggests (2) may be the primary objective. Greater clarity on this issue would be valuable.

The authors also discuss the selection of their proposed quality assessment instrument, but it is unclear what the purpose of quality assessment will be for this review i.e. how will it be used in the synthesis? Risk of bias will may not be important where the objective is simply classification, but will be where the objective is evaluation.”

We would be grateful if you could address the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns.
Our response

Thank you for this feedback. We recognise that we have not been clear enough with this and welcome the opportunity to improve the clarity of our protocol. As the Editor notes, we are doing both (1) and (2), however with the latter we recognise that we will be unable to make any firm conclusions about which behaviour change components work best based on what we expect to be a small evidence corpus. Rather, we hope to be able to map out how frequently these components of the intervention occur in effective vs non effective interventions.

We have reworded the text under ‘Aim’ to read as follows:

In this review, we aim to:

a) identify the behaviour change components reported in the published literature of swallowing interventions for patients with head and neck cancer.

b) Examine how frequently these behavioural components occur in interventions deemed to be effective vs non effective.

We have tweaked the abstract to be consistent with the changes made. We have expanded the section on data synthesis.

In addition to the above changes, we have added the following to the Discussion.

First, at the end of par1 of discussion (p12) we added:

‘As this approach is new in the field, it is not our intention to be conclusive about which BCTs are most effective. We do however wish to note how frequently they are reported in interventions deemed effective vs non effective. This mapping of information will be useful in aiding the selection of content for future swallowing interventions. While it will not be possible to conclude that the BCT itself is responsible for effects, any such observed covariance of intervention components with effectiveness will help point intervention designers in the right direction.’

And par 2 of discussion (p12):

‘We will report on the quality of the included studies, but as we do not anticipate any pooling of data or meta analysis, studies with poorer quality ratings will be retained. Nonetheless, we see value in performing a quality assessment: we believe that a summary of study quality will provide a useful snapshot of the methodological rigor of previous studies in this field and expands upon previous work that aimed to describe the quality of clinical trials in swallowing rehabilitation [15]. For ease of comparison, we have chosen to use the same quality assessment tool used in the review by Carnaby and Madhavan [15]. Discussion about quality assessment will be integrated into our narrative synthesis. It will help contextualize findings and as suggested by Popay and colleagues is also helpful in assessing the robustness of the synthesis [31].’
And as a concluding remark:

‘Better specified interventions are more easily replicated and while it is not an explicit intention of the review, raising awareness of this may be a welcome influence on intervention designers. This review adopts a new framework that we hope will help clinicians identify and begin to understand the behaviour change components of the complex therapy interventions they provide to their patients. In recognising complexity, we are presented with new challenges in the quest to assimilate the evidence for these interventions. As articulated by Petticrew [33], it may be necessary to expand our enquiry from ‘what works’ when swallowing interventions are delivered to ‘what happens’ that might make them work. We are required to explore a broader question to ascertain what has happened in previous interventions, as opposed to focusing solely on intervention effects. For a field which is relatively new to evidence synthesis and with relatively few high quality randomised studies, this approach offers a way of systematically gathering the available evidence as a first step to developing hypotheses for further testing.’