Author's response to reviews

Title: Practical health co-operation - a cluster randomised study protocol: The impact of a referral template on quality of care and health care co-operation

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Author's response to reviews: see over
Reply to the reviewer’s general comments (first two paragraphs of reviewers report):

1. The reviewer rightly identifies many of the difficult aspects with research at the border between primary and secondary care. The project tried to cross some of the invisible boundary between the care levels by including input from local GPs in the planning process. However, the reviewer’s assumption that the project is lead from a hospital based team is true, although one of the authors is a former GP.
2. To further highlight that this study does not intend, primarily, to reduce the number of referral, but to rather improve care, the following paragraph was added to the article:
   In addition the authors recognise that many referrals from primary to secondary care are made not only to identify major pathology. Referrals are also made to reassure patient, reduce medicolegal risk, obtain a second opinion or handing over of care[51]. The authors fully appreciate these as valid reasons for referral. We, therefore, do not aim to reduce the number of referral, but rather assess the effect on hospital care of improved referrals.

Framing the study:

1. Added the following text describing the role of GPs as gatekeepers in Norway and the health care system in general: In Norway each individual has a regular GP. These GPs act as gatekeepers to secondary care. The health care system is relatively uniform throughout the country. In the study area access to specialist care is practically impossible without a GP referral, whereas some access is possible in other areas of the country.
2. See text changed for point 1.

Major compulsory revisions:

1. References
   a. Changed reference 4 to the English version of the report, and apologise for the language confusion
   b. Changed reference 6 from a conference proceeding to a reference referring to a relevant journal article
   c. The reviewer is, of course, entitled to express concern regarding the background reading of the authors. All articles cited have been fully read by HW. In reworking the article all references have been reviewed with regards relevance and content. Following change has been made:
      i. changed wording and removed one reference in first sentence paragraph 3 of background section
The presentation of reference 19 has been changed slightly, hopefully less sloppy. The authors feel that the presentation, as it now stands, represent the findings of the review, as relevant to the current study. The text now reads: A recent Cochrane review on interventions to improve outpatient referrals from primary to secondary care concludes that surprisingly few interventions on the referral system have been rigorously evaluated. Many of the studies evaluated focussed only on referral rates or referral quality. The review highlights the complexities of research in this area, especially as no single study managed to present findings on all aspects of the referral process (referral behaviour, management of non-referred patients, secondary care management of patients, the flow of patients through the referral system, patient outcomes and satisfaction and resource use). However, structured referral sheets and local education interventions have an impact on referral rates [18].

e. There are still several references in Norwegian. These represent national guidelines which are not available in English.

2. There is no mention of a pilot study, as no pilot study has been carried out. This is now referred to in the manuscript as: No pilot study has been carried out. To ensure acceptability of the intervention, GPs were invited to, and participated in, the development of the referral template. To ensure feasibility, the authors have collected all data specified in the protocol from the 20 patients included first. To ensure an adequate uptake of the intervention regular reviews of all referrals received at UNN Harstad will be undertaken.

The second point, regarding effect size, is rather unclear. I assume this is related to the sample size calculation. Under ‘sample size’ the text clearly states that an effect size of 10% was decided to be clinically interesting, based on clinical judgment. With regards the intraclass cluster coefficient (which is often obtained from pilot studies, although with high imprecision) estimates from other studies are presented in the manuscript.

3. The term ‘collated’ dropped. A section added under ‘study outcomes’ which describes better how the quality score is calculated: The quality score we will calculated as adherence scores (number of quality criteria met divided by number of applicable criteria expressed as a percentage) as illustrated by Ashton[33]. If a criterion is applicable, but no information can be found (applicable, but not answerable), it will be noted “not met” for statistical purposes[34]. Weighting of the criteria based on clinical importance will not be used, as this adds complexity, without adding much to the clinical findings, a finding further discussed by Lyons and Payne already in 1975[35]. Similar information regarding the calculation of the quality score has therefore been dropped from the ‘statistical methods’ section.

4. Added a section on why we expect to achieve the sample size estimated: Based upon a review of patient data at UNN Harstad from 2008, the study is expected to achieve this relatively high inclusion number by recruiting over a two-year period (personal data).

5. Tried to clarify the paragraph by adding an introductory sentence: To correct for clustering the design effect (DE) may be calculate as DE = 1 + ρ(m-1) where ρ denoted the intracluster correlation coefficient (ICC) and m is the size of each cluster.
6. Sentence added to explain the term ‘simple’: Each unit of information specified in the referral template (e.g., presence of weight loss specified) will provide one point in the scoring system, with no weighting applied.

7. Changed the text to highlight that this study is still ongoing, and not completed: A recent study protocol describes a similar project within Mental Health Care[48], although this study is still ongoing.

*Minor essential revision:* Numerous grammatical errors corrected after text was submitted for grammatical/linguistic correction. Details of all changes are available upon request.

*Discretionary revisions:* Flow chart demonstrating how patients will be recruited into the study provided.