Reviewer’s report

Title: Design of a study evaluating the effects, health economics, and stakeholder perspectives of a multi-component occupational rehabilitation program with an added workplace intervention. A study protocol.

Version: 0 Date: 26 Sep 2017

Reviewer: Chris Main

Reviewer's report:

Comments

It has been a pleasure and a privilege to be asked to review this impressive protocol.

Abstract

1 Clearly written " although the term "effect" does not distinguish clinical, occupational and health-economic outcomes.
2 The use of mixed methods is important in such a study.
3 The term "heterogeneous patient group" needs to be more clearly specified since the possibility of post-hoc sub-group analysis (if sufficiently powered) might be of interest on conclusion of the study.
4 The design permits only the value of an additional workplace intervention.
5 There appear to be two groups targeted specifically for qualitative studies i.e. rehabilitation therapists and "stakeholders involved in the workplace intervention". Who are these stakeholders?

Background

6 The literature review is comprehensive and appropriate but Ref 13 is obscure. Can further details be provided or can it be replaced by a more accessible reference?

7 The authors are right to point out that many programs are disease specific, but there is often a reason for this as the obstacles to successful and sustained return-to-work may vary across conditions. Can a stronger clinical or occupational reason than simple convenience be found?
for convenience (and perhaps implementation) be found to support the provision of a
generic program?
8 The objective is clearly stated but ICPC-2 should be documented in full, with the
abbreviation in brackets) on the first occasion that it is mentioned.
9 The inclusion of a heterogeneous group of HCPs to deliver the ACT component raises
questions about competency and it is acknowledged that to date the ACT approach has not
featured strongly in occupational therapy. Safeguards in training to competency and some
sort of check on fidelity of implementation therefore should be added to the study.
10 The description of the Norwegian sickness absence system is helpful. Does it not raise the
possibility of a closer evaluation of sick leave coverage as part of the study?
11 Do the authors have confidence in the GPs allocation of diagnoses?
12 The sample size calculation appears to be satisfactory.
13 The arrangements for participant identification, recruitment and randomization appear to be
satisfactory
14 The description of the clinical interventions is clear, however further detail is required on
how the "relevant stakeholders" are to be chosen and involved in the work planning
component.
How is the engagement of employers in the work-related problem solving to be evaluated?
15 What lessons might be drawn from this important aspect of the study?
16 The Objectives are clearly stated
17 The ability to use Register data is a particular strength of the studies
18 The primary and secondary outcomes are relevant and appropriate although, as stated
above, there is an opportunity to examine the influences on time to return to work by
treating it also as a continuous variable (with possible banding of time to return if the
outcome distribution permits (rather than only as a dichotomous outcome).
19 I leave other assessors to comment specifically on health-economic outcome (but it seems
reasonable to me)
20 The ITT and per protocol analyses are appropriate
21 The proposals for qualitative analysis appear to be appropriate
22 Please clarify how the results from this study might be generalizable to other contexts
23 The researchers should consider the possibility of "dismantling" the heterogenous group post hoc since there may be possible to identify differences in outcome associated with initial participant characteristics.

24 There has been no discussion of the potential of multivariate analyses on predictors of outcome. While certainly the numbers in the study may restrict such an analysis (and indeed also post-hoc sub-group analyses, it may suggest opportunities for treatment targeting which could be undertaken in subsequent studies.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.
Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:
Acceptable

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