Reviewer's report

Title: The clinical and cost-effectiveness of an ultra-brief intervention for common mental health syndromes in primary care: study protocol for a cluster randomised controlled trial

Version: 2
Date: 8 December 2014

Reviewer: Catherine D'Este

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Major Compulsory Revisions

Recruitment / participation

It would be good to have a bit more clarity around recruitment. The aim (as specified at the end of the Background Section) is to evaluate UBI in individuals presenting with mild to moderate mental health problems. Under the Participants Section, eligible patients are stated as those identified by their GP during a routine appointment; and under Recruitment methodology and randomisation (paragraph 2) patients with “common mental health problems” are screened for eligibility using the K10. Is the plan for GPs to routinely administer the K10 as a screening instrument during a presentation for any reason? ie - are eligible patients all individuals attending for any reason or those who are specifically presenting to a primary care physician for mental health problems? If the latter (ie attending for mental health problems (or “common” mental health problems)), what is the definition of these mental health conditions / presentations? Will the GP undertake the screening during the presentation? At what stage and by whom is consent obtained?

Participants, paragraph 2, last sentence: If participants’ scores increase beyond 35 and they are in the intervention group but have fewer than two session of UBI will they be excluded? Will all individuals in the control group whose score reaches 35 or more during the study be excluded?

Measures

The primary outcome is referred to in Hypothesis 1 as “clinical outcomes”, defined as change in K10 and HADS from baseline to 26 weeks (first sentence of the Outcome measure section), improvements in K10 under the Economic evaluation section, and in the analysis section “improvements in mental health”. The analysis description indicates that outcomes are final follow-up scores adjusted for baseline scores (rather than change scores). Can the primary outcome be clearly specified – is it a change score, or followup score adjusted for baseline score?

Are secondary outcomes of K10 at 8 and 12 weeks also changes scores? Hypothesis 2 specifies that functioning (work and social relationships) will also be
measured at 8 and 12 weeks, but the outcome measures section specifies that this scale will also be obtained at 26 weeks. When will the EQ-5D measure be obtained – at all three follow-up periods as well as baseline?

Statistical methods:
There is no mention of statistical power or analysis for secondary outcomes. What is the basis for the ICC estimate? Intention-to-treat analysis will be undertaken but there is no specification of how missing data will be considered.

Minor Essential Revisions

Hypothesis 3 related to cost effectiveness, but this seems to have already been included in Hypothesis 1.

Design: There is clustering at both the GP and the practice level

The HADS has an anxiety subscale and a depression subscale – will these be considered as outcomes or only the overall scale? K10 and HADS are commonly used as categorical measures due to the skewed distribution of the scores and because the defined categories have clinical meaning; what is the rationale for using these as continuous variables?

It seems that outcomes will be analysed separately for each followup time – is that correct? Is there a plan to include all endpoints in a single analyses and compare changes over time between intervention groups?

Data on satisfaction will be obtained from clinicians and from a sample of participants – how will these data be used?

The cost effectiveness analysis will include cost savings from estimated reduction in contacts with health service providers and in time and travel costs for patients – how will these be estimated?

Typographic / editorial comments
Participants, paragraph 1, second last sentence: “...scores falling between 30-35 on the K10 were potentially below diagnostics threshold, and were therefore included.” Does this mean that individuals with scores in the range 30-35 were included in the references studies?

Recruitment methodology and randomisation, first paragraph, third last sentence: “Of the sixty-three GPs who originally consented to practice....”; should this be “participate” instead of “practice”?

There is some mixing of past, present and future tense throughout the methods section - it would be good to be consistent with the use of tense where appropriate.

**Level of interest:** An article whose findings are important to those with closely
related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests