Author's response to reviews

Title: A multi-site controlled trial of a cognitive skills programme for mentally disordered offenders

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Author's response to reviews: see over
Ms Catherine Olino
BMC Journal Editorial Office

Dear Ms Olino

**MS 1332665967640466**

**A multi-site controlled trial of a cognitive skills programme for mentally disordered offenders**

Please find attached this manuscript which has been revised to take account of referees’ feedback as follows:

**Referee 1: James J. Tapp**

Item 1 – include a study design subsection

*Response: As this would be a very small section, we have amended the heading on p7 to “Design and Participants” and amended the text as follows:*

“This quasi-experimental controlled study involved the participation of 121 male patients.....”

Item 2 – report exclusion criteria

*Response: we thank the referee for drawing our attention to our omission of the exclusion criteria of mental instability. We have added on page 8:*

“Exclusion criteria included patients who were mentally unstable and/or who posed a risk of violence to the researcher”

Item 3 – offer a more explicit description of the content of treatment as usual.

*Response: our reference to ‘other similar cognitive skills interventions’ related specifically to similar programmed cognitive skills interventions, such as R&R and*
ETS. For clarification we have stated this explicitly on p10 in the Treatment as Usual section. Referee 2 has also requested that we provide greater information about treatment as usual and we have also provided this here (see our response to Referee 2, Item 6 below).

Item 4 – offer a more explicit rationale for the choice of distal outcomes.

Response: On p14 in the procedure section we have added the following explanation:

“Only the primary outcome measure (MVQ) and the brief and relatively simple LoC measure were repeated at follow-up in order to reduce demand and maintain patient cooperation. It was not possible to collect follow-up informant data on the DBSP measure due to staff turnover on the wards.”

Item 5 – remove the REC reference number

Response: we have done this.

Item 5 – A more clearly articulated theory of change for the R&R programme for the purposes of selected outcome assessments would help the reader in making sense of this [locus of control] finding.

Response: On p12 in the outcome measures section we have added the following clarification of the locus of control:

“Interventions should aim to increase a person’s internal orientation as research has found that people who have an internal locus of control (who perceive they are in control of life events) are more likely to participate in treatment and have more positive outcomes, whereas those with more external orientations (who believe life events are outside of their control and, for example, due to luck or fate) have been found to have poorer outcomes from treatment [34]”

Item 6 – Report the inter-rater reliability co-efficients of the DBSP if available; discuss the potential limitations with conducting multi-site trials and clustering data (e.g. Peduzzi et al., 2002) Analysis of Randomized Controlled Trials. Epidemiological Reviews, 24, 1, 26-38) to support the conclusions that R&R2 is responsive to both levels of security.

Response: Inter-rater reliability co-efficients of the DBPS have not been published however, to minimise between-rater differences, the same member of staff was required to complete the questionnaire at Time 1 and Time 2. We have clarified this on p14 in the Procedure section as follows:

“To minimise between-rater differences, the same staff member was asked to complete the questionnaire at Time 1 and Time 2.”
On p14 in the limitations discussion we have emphasised that this affected ratings on the DBS as follows:

“..high levels of staff turnover on wards meant that there were higher rates of missing informant data on the DBSP (that could be rated by the same member of staff across the two time points).”

On p14 we have added the limitation of conducting a multi-site trial incorporating two levels of security (and we have clarified that the reason for this was to optimise recruitment – see our response to Referee 2, Item 5) as follows:

“Multi-site trials are thus not without limitations due to within and between-site variations among procedures and participants. This ‘clustering’ of data is particularly salient to our inclusion of participants from low and medium security sites.”

Item: 7 – check the reference list for minor typographical errors

This has been done.

Referee 2: Maroesjka van Van Nieuwenhuijzen

Item 1 - The introduction is lacking a theoretical framework. What is the explanation model of the intervention? What are the goals of the program? What is known on the goals/outcome measures in relation to the population under study? Thus, which variables (outcome measures) are examined to answer the question whether the program is effective in reaching the goals in this particular population? Now, a list of outcome measures is given, without any rationale whatsoever (p 6-7).

Response: See item 15 below which relates back to this item.

Item 2 - P7. The population is defined rather vaguely. The inclusion criterion states ‘diagnosis or history of severe mental illness’. This is a rather heterogeneous group, as it must include different mental illnesses.

Response: On p8 we have provided some examples of severe mental illness for those who may not be familiar with disorders that are included under this commonly used umbrella term, e.g “schizophrenia, schizoaffective disorder, bipolar disorder”.

P14. There are 2 different illnesses in the population under study: psychotic disorders and mood disorders. How are they divided over the groups? How does this influence the results? The intervention may work better for the group with illness A than for group with illness B.

Response: as stated on p16, the majority - 87.6% (N=106) - of the sample had psychotic disorders and 12.4% (N=15) mood disorders. The division of disorders across the two conditions was similar – psychotic disorders N=59 and mood disorders N=8 in the treatment condition and psychotic disorders N=46 and mood disorders...
N=8 in the control condition. Whilst we agree it would be interesting to know whether there are subgroup differences in outcome, there is insufficient power to conduct within-group analysis by illness subtype because the number of patients in the mood group are too small to provide meaningful results.

Item 3 - P7. ‘all participants were referred by their clinical team...’ Were offenders asked to participate, or is the intervention an obligated part of their treatment. The text is not clear on this point. In addition, the authors should make clear how respondents are assigned to treatment and waiting list condition? Was the intervention introduced to all residents of the facilities, and thus was randomly assignment possible? Or is the intervention offered to new patients, so that the treatment group consists of the first X patients.

Response: We have clarified this in the procedure section on pages 13-14 by stating:

“All patients at the facilities who were considered sufficiently mentally stable and who were ‘ready’ for this type of treatment and likely to benefit from it were referred by their clinical teams. The treatment was not mandatory. A waiting-list controlled design was applied in the study with group/control allocation being determined by the order of the referral. Once the number for a group had been reached, the remaining patients were put on a waiting list for the next group.”

Item 4 - IQ scores should be provided for both groups. How is IQ measured? Does IQ influence the results of the intervention? In addition, if there is a considerable amount of respondents with an IQ between 70-85, have the authors considered the specific characteristics when testing the respondents, and in the instruments used?

Response: The patients were not in a learning disability facility and those who had a history of learning disability were excluded from the study. However we agree with the points raised about borderline IQ in this population. In the UK IQ scores are not routinely obtained for all patients in secure facilities and the IQ was not assessed as part of the study thus we are unable to provide IQ scores. For clarity therefore, on p8, we have removed the reference “IQ<70” in order that readers do not mistake this as a definition of learning disability (which it is not, as this is only one of the defining factors involved).

For our response to the query relating to consideration of specific characteristics when testing respondents, please go to item 7 which also addresses this topic.

Item 5 - P7. Respondents come from both medium and low secure facilities. Authors should provide more information on these facilities. What is the difference between both facilities? Why are both facilities included?

Response: We have added to the participant section on p8:

“In order to optimise recruitment, patients from both low and medium security settings were invited to participate in the study. These settings differ in their staffing
arrangements and physical security measures. Patients in medium security are those who present a serious danger to others and have the potential to abscond. Patients in low security are considered to present a less serious danger to others and security measures are intended to impede rather than prevent absconding. Usually patients go through an integrated care and treatment pathway that spans one or more levels of care.”

Item 6 - P7/9. Authors should provide more information on what the treatment as usual consists of. Is the intervention program given on top of the treatment as usual? Is the current study an add-on study?

Response: The intervention was provided on top of the treatment as usual, however during the period of study control participants were not permitted to attend the R&R2 group or other similar cognitive skills programmes (we refer to this on p10 in the Treatment as Usual section, and have clarified the meaning of similar cognitive skills programmes as per our response to Referee 1, Item 3 above). It is also stated in the procedure section on p14 that information about other interventions was not collected and thus we were unable to control for interventions provided in the normal course of treatment (defined in the manuscript as treatment as usual, or TAU). However to give readers an idea of interventions that are commonly provided in these settings, we have added the following to the Treatment as Usual section on p10:

“Interventions that are commonly provided in medium and low secure settings include pharmacological treatments, individual and group occupational and psychological therapy, the latter including cognitive behavioural therapy for psychosis, anxiety, depression, substance misuse and relapse prevention.”

Item 7 - No information is provided on the appropriateness and reliability of the scales in people with borderline intelligence. In addition, I wonder whether psychotic patients can complete the questionnaires. No information is provided on the appropriateness and reliability of the scales in a psychotic/mood disorder sample, except from the LoC scale.

Response: Patients who are acutely unwell were not referred for participation in the study. As requested by Referee 1 we have explicitly stated exclusion criteria on p8 in the method section. The measures selected are commonly used for research and clinical purposes in mentally disordered offenders (who as the reviewer rightly points out are often complex individuals with severe mental illness, high rates of comorbidity and lower IQs) and the results have been published extensively in research on this population. Furthermore, patients completed the measures under close supervision of the researchers who read and/or explained items to patients, if required. There are therefore no reasons to believe that they were not understood by the participants or gave unreliable results.

We have added under the Outcome Measures section on p11 “These measures are commonly used with mentally disordered offenders”
Item 8 – No information is provided on treatment integrity.

Response: We have added on p14 in the procedure section:

“Treatment integrity was ensured by the highly structured style of this manualized programme (for both facilitators and mentors), regular attendance at steering groups by site representatives that included group discussion and supervision by SY a clinical and forensic psychologist and programme author and, by arrangement, supplemental individual supervision sessions.”

Item 9 – p14. Groups differed in level of security. Did the authors control for level of security?

Response: ANCOVA allows the exploration of differences between groups while statistically controlling for one or more additional continuous variables. Level of security is a categorical variable (low or medium) and there is no non-parametric alternative.

However since significantly fewer TAU participants were drawn from low security, we compared group participants with TAU participants on baseline characteristics and outcome measures and found no significant differences between these two groups in their age, history of admissions to secure care, number of previous convictions, current motivation to engage in treatment, and outcome measures assessed at baseline (see p16 in Baseline Characteristics section, and this is also discussed on p17).

Item 10 – P15. Table 2. Only information on the total scales is provided and not on the subscales. Do groups differ on the subscales of the instruments?

Response: This table compares the differences between group completers and noncompleters on baseline characteristics and outcome measures assessed at baseline. The latter compares N=52 with a low N=15 for the noncompleters. Increasing the number of scales is likely to result in a high risk of Type II errors therefore it is inappropriate to conduct analysis on all the individual subscales within these measures. The issue of interest is to obtain a broad perspective on differences between these two groups.

Item 11 – It would help the reader in interpreting the data to provide minimum and maximum scores for each scale in the Methods section.

Response: We have provided this information as requested.

Item 12 - P17. The statement ‘.findings support the feasibility…. , and further extend its utility to low secure settings’ is rather strong, considering 25 respondents from low security settings in the intervention group and only 7 in the control group. At p18. The second aim, the evaluation of the intervention, is discussed. In the
introduction the evaluation was presented as main aim, and the completion of the intervention as secondary. In the discussion, I would present the main aim first.

Response: We have amended the text on p19 to say “support the feasibility of delivering the programme to MDOs in medium and low security”. For the second part of this item, see our response to item 13 below as these items seem to be related.

Item 13 - P17. The discussion section starts with discussing ‘an important finding was the low dropout rate, supporting the hypothesis…’

Response: Group completion rates are usually reported before outcome in this type of study and we are grateful to the reviewer for pointing out that the important aim relating to group completion had become ‘lost’ at the end of the introduction. We have therefore amended the sentence at the end of p7 as follows:

“This study aimed to evaluate the completion rate and effectiveness of R&R2 MHP.....”

In addition we have added to the beginning of the Discussion on p19:

“This study aimed to evaluate the completion rate and effectiveness of R&R2 MHP.....”

Item 14 - P19-20. The not findings are discussed in the light of previous research. However, the authors do not explain why they have not found effects on all scales. In what way does the current study differ from the previous studies (population, intervention) which may explain the non-findings?

Response: On p22 we have added our thoughts on this point as follows:

“Nevertheless, in common with many multisite studies, a significant treatment effect was not found for every scale at outcome and, despite attempts to standardise the treatment and research protocols and ensure programme integrity between the sites, there may have been variation in standards of delivery. Another possible explanation may be that most outcome measures were not re-administered at follow-up. The treatment effect at follow-up was sustained for violent attitudes and although there was no significant difference in locus of control between the two groups post-treatment, a small significant effect was present at follow up. Had other secondary outcome measures been repeated at follow-up, it is possible that a similar enhanced treatment effect may have extended to......”

Item 15 - P20. The section about the development of the R&R intervention touches theoretical framework, and should be discussed in the introduction (see my comment 1)

Response: Thank you for this suggestion. We have moved the section relating to the theoretical framework and development of the R&R intervention from the discussion
on p20 and revised the second paragraph in the Background section on p4 as follows (references have also been re-ordered and numbered):

“There is general agreement that criminal history, pro-criminal attitudes, associates and antisocial personality represent the “big four” risk factors [4] and it follows that these must be primary targets for change. Thus, a number of manualised programmes have been developed that attempt to reduce the rates of reoffending through cognitive skills training [5] as research indicates that offenders either lack or have poor cognitive and social skills [6]. The most widely adopted programmes have been the 36-session Reasoning & Rehabilitation programme (R&R) [7, 8] and 22-session Enhanced Thinking Skills (ETS) programme [9]. R&R was the first manualised cognitive-skills programme designed to specifically address antisocial and offending behaviour and accredited for use by the correctional services. It was developed by selecting cognitive techniques from programmes that had been successful in reducing re-offending. It was designed to help offenders develop their cognitive and social skills and values and, thereby, improve their pro-social competence and decrease their reoffending. The major components of R&R are self-control, meta-cognition (thinking strategies as a means of regulating behaviour), social skills, interpersonal cognitive problem-solving skills, creative thinking, critical reasoning, social perspective-taking, values enhancement, emotional management and helper therapy (peer mentoring) [10, 11]. Thus the programme aims to modify cognitive skills and values; problem-solving skills are but one aspect and, although important, are secondary to the primary aim of pro-social competence. R&R has been widely researched; meta-analyses have supported its efficacy in a variety of settings with heterogeneous offenders and showing programme attendees were 14% and 21% less likely to reoffend compared with controls when delivered in institutional and community settings respectively [12, 13].”

Item 16 - P21. IQ has not only been association with non-completion rates but also with other concepts (see my comment 4).

Response: This limitations section considers characteristics that have been empirically reported to be associated with non-completion rates, the latter being the dependent variable of interest. These include IQ, self-esteem, impulsivity and psychopathy (i.e. independent variables). Reporting factors that are associated with IQ (i.e., with IQ being treated as the dependent variable) has no relevance to the issue being considered.

Item 17 - The authors use a lot of abbreviations, which is confusing for the reader.

Response: BMC Psychiatry includes a standard section listing all abbreviations at the end (see p24).

We look forward to hearing from you.

Yours sincerely
Dr Susan Young