Author’s response to reviews

Title: Jail-to-Community Treatment Continuum for Adults with Co-Occurring Substance Use and Mental Disorders: Study Protocol for a Pilot Randomized Control Trial

Authors:

Richard Van Dorn (rvandorn@rti.org)
Sarah Desmarais (sdesmarais@ncsu.edu)
Candalyn Rade (cbrade@ncsu.edu)
Elizabeth Burris (enburris@ncsu.edu)
Gary S. Cuddeback (cuddeback@mail.schsr.unc.edu)
Kiersten Johnson (kijohnson@rti.org)
Stephen Tueller (stueller@rti.org)
Megan Comfort (mcomfort@rti.org)
Kim Mueser (mueser@bu.edu)

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Author’s response to reviews:

Annet Kleiboer, PhD
Associate Editor, Trials
VU University Amsterdam

Re: TRLS-D-16-01020 “Jail-to-Community Treatment Continuum for Adults with Co-Occurring Substance Use and Mental Disorders: Study Protocol for an Uncontrolled Open and Randomized Control Trial” (revision)
Dear Dr. Kleiboer:

My colleagues and I are very pleased to revise and resubmit our paper for further review in Trials. Enclosed you will find a revised version of the manuscript with the revisions highlighted. The revised manuscript has been strengthened thanks to the reviewer’s helpful suggestions for clarification on several points.

In what follows, we list the reviewer’s comments (in italics) and describe our response to each:

EDITOR

- Trials requires the submission of a populated SPIRIT checklist and figure for all study protocols. We appreciate that you have included the checklist, but please also ensure the figure is included as an attached figure file (http://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol). Both the figure and the checklist should also be referenced in the main manuscript text. A Word file of the figure can be downloaded here: http://www.spirit-statement.org/publications-downloads/. (figure: http://www.spirit-statement.org/wp-content/uploads/2013/01/SPIRIT-Figure.doc)

We added the SPIRIT figure (Figure 2) to the manuscript. The checklist and figure are now referenced in text (see page 7).

- Please remove the ethical approval and funding documents from the additional files, we cannot publish these.

We removed the ethical approval and findings statements from the additional files.
- Please ensure the title conforms to journal style for study protocol articles. The title should follow the format “_________: study protocol for a randomized controlled trial.” Please note that the title in the submission system should match that of your manuscript.

We revised the title to conform to the journal style.

REVIEWER 1

I enjoyed reading this protocol very much. The authors describe their aims clearly and concisely. It is my belief that this study will advance research and practice for inmates with CODs and is therefore, a worthwhile contribution to the literature. However, I do have some remarks:

1. I would like to see a flow diagram according to the CONSORT guidelines. This would improve clarity regarding the various steps of the study.

We have added a flow diagram for the RCT.

1. In the following paragraph: “Treatment group. Inmates assigned to the treatment group will participate in the DDMI-IGT continuum. Between four and eight groups of participants will complete the DDMI-IGT treatment during the RCT, depending on how many participants are enrolled in each IGT cycle.” I would like the authors to clarify (for replication purposes) up to how many patients they are planning to include in these treatment groups.

No more than 8 inmates will participate in IGT at any given time (see page 13).

1. Regarding the following paragraphs: “Additionally, we will collect sociodemographic data for participants, including diagnosis, race/ethnicity, age, and sex, obtained though clinical and administrative records. Inclusion of these variables will allow examination of potential differences in treatment outcome as a function of each variable and, controlling for sociodemographic factors in statistical analyses.” AND “Although not a primary aim of this study, an important clinical question is the extent to which the intervention might be differentially effective as a function of inmate characteristics at treatment entry.” Although, the
sample size of 60 might be appropriate given the developmental focus of the current study. I have my doubts whether it is appropriate to assess subgroups of patients given the limited sample size.

We agree that caution is warranted; all statistical analyses will be implemented in an appropriate manner.

0 In the first paragraph there is a typo: “though” should be “through.”

Fixed.

0 The authors mention in “Aim 1” that: “All transcribed qualitative data from interviews and focus groups will be coded according to coding guidelines which will concentrate on deductive themes focusing on the feasibility and acceptability of treatment programs and protocols.” Is there any reference for these guidelines available that you could cite?

That text is supported by our reference to Weber’s 1990 book.

0 The authors mention in “Aim 2” that: “We will examine baseline clinical, legal, and demographic differences between groups to determine if RCT treatment group randomization was successful.” In which way are you going to examine this? I would like to remind you that according to the CONSORT guidelines significance testing of baseline differences in RCTs should not be performed.

We appreciate the reminder. However, given the overall lack of RCTs that have taken place among adults with co-occurring mental and substance use disorders in jails, we believe it is important to examine the randomization, which we will do via a series of bivariate associations. This process was raised by reviewers from the NIH study section and was added to the procedures upon re-submission.

In summary, the enclosed protocol paper describes both an open, uncontrolled and an randomized controlled trial for adults with co-occurring substance use and mental disorders in jails. The National Institute on Drug Abuse funded this research (Award Number
R34DA036791). All authors meet the Journal’s criteria for authorship and agree to the submission and copyright transfer.

Thank you once again for the helpful review. We hope that the revisions are satisfactory. My colleagues and I are very pleased at the prospect of having this paper published in Trials.

Sincerely,

Richard A. Van Dorn, Ph.D. (corresponding author)
Sarah L. Desmarais, Ph.D.
Candalyn B. Rade, Ph.D.
Elizabeth N. Burris, BS
Stephen J. Tueller, Ph.D.
Kiersten L. Johnson, Ph.D.
Megan L. Comfort, Ph.D.
Gary S. Cuddeback, Ph.D.
Kim T. Mueser, Ph.D.