Author’s response to reviews

Title: A study protocol to assess the feasibility of conducting an evaluation trial of the ADVANCE integrated intervention to address both substance use and intimate partner abuse perpetration to men in substance use treatment

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Author’s response to reviews:

Reviewer #1: Overall, the study protocol is well-written and organized. This study addresses an important unmet need, specifically services for those individuals struggling with substance abuse and intimate partner abuse (IPA).

Thank you for your supportive comments.

Background

* Page 4, line 3: the authors indicate that there are few instances of appropriate referral, treatment completion, and attendance/uptake among those receiving IPA services who also struggle with substance abuse. More information providing examples of such information would be helpful to provide greater context.

The following additional information has been included.

In one US study, only 17% of 658 men seeking alcohol treatment who had perpetrated IPA in the past year were referred to a perpetrator programme by the alcohol treatment service, and only 15 (13%) enrolled in the programme [27]. Among 286 males convicted for intimate partner violence and court-mandated to attend a community-perpetrator programme in Spain, a significantly higher rate of intervention drop-out was reported among men with alcohol problems (36% vs. 23%, p <.05) [28].

* Page 4, line 12-27: This section is very thin on details and as such, requires more fleshing out. The authors indicate that “integrated interventions to address both IPA and substance use show some promise and make clinical and economic sense.” More information is needed to clarify specifically what authors are referring to in terms of “promise” and “clinical/economic sense”. Also, given that some integrated substance abuse and IPA programs already exist, why is a new integrated program needed? What are the limitations or gaps in prior integrated services that the current intervention addresses? In short, what is the rationale in terms of how ADVANCE contributes the science behind such integrated interventions? More information is also needed regarding the operationalization and justification for a “multifactorial approach”, the importance of concurrent IPA and substance abuse treatment, and more “holistic” strategies.

This has been updated to “Few perpetrator interventions have been trialled among men who use substances [28]. A recent review of interventions to reduce IPA perpetration by men who use substances identified only nine trials; three of which were conducted in substance use treatment services and two were among men who had been arrested for IPA or court mandated to receive the intervention [28]. Initial reviews of IPA interventions conducted concurrently with alcohol treatment [29] or integrated interventions that address both IPA and substance use [28] show...
some promise but were not superior to treatment as usual [28]. Some interventions to address IPA in men who use substances present a simplistic model of inebriated physical violence and struggle to integrate issues of gender, non-physical abuse and to fully consider the impact of a substance use lifestyle. Recent research has identified that it is not one factor that explains causal pathways into IPA, but rather a multi-level and multi-factor explanation is required [17,18,30]. A nested ecological model identifies factors at 4 levels, including structural factors such as patriarchy, sub-cultural factors, for example, high tolerance for general alcohol use, familial factors, including modelling from family of origin and social learning theory, and individual factors such as high anger or high impulsivity [31]. This multifactorial response requires a more nuanced understanding of the roles of substance use in IPA perpetration that is wider than intoxicated abuse. Withdrawal and craving present as many risks as intoxication and intensify coercive control [18]. Many perpetrators report psychological problems and explain IPA as a shared response to anxiety or depression and anger, often from emotional insecurities shaped by negative childhood experiences, and mediated by substances [17].”

Finally, there is no information on the theoretical basis for the ADVANCE. Although authors detail the intervention in the methods section, it would be important in this section as well as to summarize the various components/strategies of ADVANCE, the theoretical justification for each component/strategies, prior research behind ADVANCE or its components/strategies, as well as clear explication regarding how ADVANCE innovates within the limited field of integrated IPA and substance abuse treatment.

Additional information now included “Intervention arm

The TIDieR (Template for Intervention Description and Replication) Checklist was used to describe the intervention [38] (Table 3). The Behaviour Change Wheel, incorporating the COM-B model (capability, opportunity and motivation for behavioural interventions) was used to provide a framework to develop the ADVANCE intervention [39]. The ADVANCE intervention is voluntary, i.e. men are not mandated to attend by the court. The ADVANCE intervention is manualised comprising 2-4 individual sessions (2 need to be completed before beginning the group intervention) with a keyworker to set goals, develop a personal safety plan and increase motivation and readiness followed by a 12-week group intervention (Figure 2) [40]. Given the high level of trauma, family disruption, abuse and neglect in this population, interventions targeting IPA in men who use substances requires a trauma-informed approach [41]. Recent approaches with forensic populations indicate that strengths-based approaches, designed for a range of learning styles, avoiding shame and judgement are more effective [42,43]. Three potential targets for effective IPA change were identified as reducing pro-abuse attitudes (including locating causality for abuse in substance use), managing distress individually and pro-socially, and learning effective, non-abusive behavioural responses within relationship negotiations. The ADVANCE intervention focuses on developing participants’ strengths and developing healthy, non-abusing relationships. Two main models to enable change were selected 1) personal goal setting, to work with individual goals, and to build genuine motivation through alignment with personal values and facilitate change by breaking larger longer term aims into specific small steps that can be more easily achieved, reinforcing motivation through these small achievements and 2) informed by the self-regulation model which suggests that building self-
management in one domain enables more effective self-management across other domains. The intervention requires individuals to set specific goals for reducing risk, such as changing substance use, and for developing a prosocial lifestyle in terms of work, leisure, health, and accommodation. Underpinning the goal-focused approach is the need to improve self-regulation of behaviours, achieved by identifying and changing cues, appraisals (thoughts), emotions, behaviours, and consequences.”

I would strongly encourage the authors to utilize the TIDieR template for intervention description and replication checklist and guide, which could be included as an additional document and referred to either in the background or methods section.

The TIDieR template has been included as table 3 and referred to in the section on the intervention arm.

Methods

* Page 5, lines 23-34: More information is needed to describe the setting and participants. How many "sites" in total will be recruited? How many participants per site and cycle (referred to later in the methods section)? What defines a "cycle"? I would indicate here that n = 108 total male participants will be recruited, as well as n = 76 female current or former partners (as indicated later in the sample size section).

Additional information has been included “108 male participants will be recruited from NHS and voluntary organisation community substance use treatment services in three regions in England (two services in London, two services in the West Midlands and two services in the South West). Sets of up to 18 men per treatment service will randomised. Three sets of the 16-week ADVANCE intervention, one in each region, will be completed (cycle 1) and a formative evaluation undertaken to inform the implementation of cycle 2 (a further three sets of the intervention, one in each region). Up to 18 men per set will randomised per cycle.

The female current or former partners of men recruited to the trial will be offered support from an integrated safety service and invited to provide outcome data for the trial. Based on recruitment figures from other evaluations of perpetrator programs [34] and a recent UK-based perpetrator intervention [35], it is estimated that up to 70% of their current or former female partners will be recruited (n=76).”

* Page 6, lines 1-13: the exclusionary criteria appears to ensure that those cases which are most imminent in terms of risk and/or hostility are likely to be screened out, (excludes cases with restraining order, current court cases, pending child protection hearings). It would be important to address in the limitations what this means in terms of prospective findings and generalizability? It would also be helpful for authors to articulate the rationale behind the exclusion criteria.
Explanations have been included

Men will be excluded if any of the following apply:

1. current restraining orders prohibiting them or anyone on their behalf (e.g. the women’s support worker or the researcher) from contacting their current or ex female partner

2. pending court cases for IPA as it is uncertain how they will be sentenced (i.e. they may not be able to participate in the trial)

3. pending child protection hearings to ensure that participating in the trial could not be used to influence proceedings

4. attending an intervention for IPA perpetration

* Page 7, lines 14-15: What is the rationale for excluding those men who indicate this is their first appointment?

Additional information has been included to explain

“Men who report this is their first appointment at the service will not be screened as they may not be enrolled in the service following assessment. To be eligible to participate in the trial, male participants have to be receiving treatment from the participating substance use service.”

* Page 9: lines 14-24: This is the first time authors mention the term "cycle" - more information regarding what this means, how it is operationalized and how many cycles.

Cycles are now explained earlier under ‘Participants and Settings’

* Page 9: lines 48-59: the information provided here on the Behaviour Change Wheel and the COM-B model is insufficient - more information should be provided explaining the theoretical background as well as existing evidence that the use of such concepts would be effective in addressing IPA. Finally, it would be helpful to the reader if authors could articulate which theoretical concepts underscore each ADVANCE treatment component.

The following has been added “Within the COM-B model, the intervention thus considered how capability, opportunity and motivation for each could be addressed and which type of intervention would be best to enact each. Thus modelling, enablement, education, incentivisation and training are included in the intervention. In the ADVANCE intervention, capability is enhanced by increasing participants knowledge and skills based on the self-regulation model. In particular, awareness around crisis planning and self-management is raised and automatic thoughts and beliefs are challenged by evaluating the consequences. Opportunity is provided to model and promote positive behaviour within intervention sessions, and out-of-session tasks to generalise learning. Each week sessions were reviewed to reinforce positive achievements.
Finally, goal planning is used to motivate participants and reinforcement of motivation is achieved through ongoing personal support and incentives.”

* Page 10, Lines 1-20: is the 12 week group intervention compulsory? This should be clarified either way.

Additional information has been included to clarify that the programme is voluntary

“The ADVANCE intervention is voluntary, i.e. men are not mandated to attend by the court. The ADVANCE intervention is manualised comprising 2-4 individual sessions (2 need to be completed before beginning the group intervention) with a keyworker to set goals, develop a personal safety plan and increase motivation and readiness followed by a 12-week group intervention (Figure 2) [34].”

* Page 11, Line 7: Authors indicate "Group sessions will be recorded…” Audio or video recording? Video is indicated later on page 12 - it would be helpful to have this information here as well.

The group sessions will be video recorded and the text has been revised to read

“Group sessions will be video recorded with participants’ consent and checked for fidelity”

* Page 12, Lines 1-27: More information is needed regarding what constitutes Treatment as Usual (e.g., individual/group/family counseling, 12-step programs, etc.)

This has been updated to include “Men in both treatment arms will receive substance use TAU including group work, individual sessions, mutual aid and opiate substitution treatment.”

* Page 13, Line 5: extra word "the" should be deleted: "of the attending the intervention…”

The typographical error has been corrected

* Page 14, lines 14-51: Authors indicate that the AUDIT and DUDIT measures will only be included at baseline - what is the rationale for not included both these measures at post-test as well?

The text has been updated to explain

“As the AUDIT and DUDIT assess substance use in the past 12 months they will not be used to measure substance use outcomes post-intervention (4-months post randomisation). Instead, the average amount on a using day and number of days substances used in each of past 4 weeks will be recorded using the Treatment Outcome Profile [39] at baseline and follow-up. The number of days in the past 4 weeks that problems with particular substances will also be recorded using The Addiction Severity Index [40] as will current treatment for substance use.”
Page 22, lines 19-21: What is the rationale behind the statement "It is estimated that around 70% of current or former female partners…"

References have been included to explain rationale. “The female current or former partners of men recruited to the trial will be offered support from an integrated safety service and invited to provide outcome data for the trial. Based on recruitment figures from other evaluations of perpetrator programs [34] and a recent UK-based perpetrator intervention [35], it is estimated that up to 70% of their current or former female partners will be recruited (n=76).”

Page 23, Line 1-24: More information is needed regarding what specific data and what specific sources to facilitate the economic analysis portion of the study - how will these data be computed?

Additional information has been added

“Questionnaires on the use of primary and secondary health and social care services and contacts with criminal justice services by men (and their female current or ex-partners) in the intervention and control groups will record quantities of resource use. This resource use will be multiplied by unit costs to estimate a cost profile for each participant”

Page 23, Lines 27-40: It would be helpful for the reader if authors could provide an example of their proposed qualitative analysis strategy "Framework analysis".

Additional information has been added

“Collecting multiple perspectives data (e.g. from male and female participants, keyworkers, intervention facilitators and women’s support staff) in a qualitative formative evaluation will provide a better understanding of the intervention’s implementation. The framework approach allows the exploration of patterns in themes across different participants and groups of participants”

Reviewer #2: A well written protocol for an important research. I only have a few comments (mostly grammatical/typing errors);

Thank you for your supportive comments

p3 lines 41-43 I would revise that sentence for more clarity/flow i.e. 3/4 men attending SU treatment in ... had committed IPA ...’ I would also expand on what you mean by ‘few had ever had support’ - support for what?

This section has been revised as suggested.

“At least three in 10 men receiving substance use treatment have been physically or sexually violent and seven in 10 men have been psychologically abusive towards their partner in the previous year [3, 8, 9, 19-21]. These rates are far higher than among the general population [12,
14. Around three-quarters of men attending substance use treatment in England had ever perpetrated any IPA towards their partner [9].”

On page 4 under Rationale, you talk about increasing reach ... do you mean interventions’ reach? This is not clear

This has been expanded

“It is hoped that delivering tailored IPA interventions in substance use treatment will increase their ability to reach men who may not otherwise be referred to perpetrator interventions and result in better outcomes for male perpetrators and improved wellbeing for their female partners”

In your inclusion / exclusion criteria, you mention several times that the keyworker will assess men's suitability to participate in the trial e.g. p6 line 14. I am not sure what this means. Will the keyworker self select suitable participants even after the eligibility criteria is ok? Why? Any risk of recruitment bias here?

This was also raised by reviewer 1 and has been addressed. Keyworkers consider the suitability of eligible clients to participate in the trial (eg. cognitive deficit or mental health problems that may limit with their ability to participate).

Also reading through your informed consent process on pg 7 I think you need to make it clear somewhere earlier on that you are taking on a staged informed consent approach. Reads to me to be quite similar to the Trials Within Cohorts (TwiCs) approach to sharing research information.

Additional information has been included “Participation in the trial requires a two-stage informed consent. Firstly, men must consent to be screened for eligibility. If eligible after screening, men then consent to take part in the trial.”

Pg 7 lines 17-19 I would rewrite this sentence or split into two sentences as it is not very clear

This sentence has been rewritten as suggested.

“This letter will inform the keyworker that their client is has screened positive for past year IPA and identify areas of risk (eg. threat/use of weapon against partner or choking/strangulation of partner) for potential further assessment by the keyworker. It will also include the name of their client’s current and/or former female partner. Keyworkers then are able to consider the suitability of their client to participate in the trial (eg. cognitive deficit or mental health problems that may limit with their ability to participate).”

Lines 26-27 I think you mean to say 'countersigned' by the researcher

The text has been updated to say countersigned.

Lines 46 again here we need more clarity on how keyworkers will assess suitability for participation
Suitability is now described earlier in this section.

Pg 8 line 36-37, what is the nature of the interviews with the women, i.e. content? I assume these may be quite vulnerable participants.

The outcome measures section describes in detail the content of the interviews. This section has now been referred to on page 8.

Pg 9 line 31 around Blinding, do you mean statisticians will be blind to participants' trial condition during recruitment or throughout the feasibility trial?

Throughout the trial. This has been updated.

Pg 11 line 7, when and how will you get consent from the group to record their session? Will this be audio or video recordings? What if someone in the group does not want the session to be recorded?

“Group sessions will be video recorded with participants’ consent and checked for fidelity. Only those consenting to being video recorded would be able to take part in the trial.”

Pg 12 under Fidelity, why have you opted for video recording? Secondly, do you have any detail on how the checklist assesses fidelity?

All group intervention sessions will be video recorded with participants’ and facilitators’ consent. Facilitators’ fidelity of the delivery of the intervention manual will be assessed by a trained observer using a pre-defined checklist for each session of the intervention. Video recordings will allow the same observer to assess treatment integrity, the degree to which a treatment is implemented as intended across sites. Sessions are videotaped for assessment of treatment fidelity, therapist skill and competency in delivering the interventions and the discriminability of the study treatments. Treatment fidelity will be assessed using an adapted form of the Yale School of Medicine Adherence and Competence Scale [37], shown to be successful at discriminating key therapy content and skill domains [38]. A series of checklists are created to tap into key unique components of specific therapies (e.g., experimental condition vs. control) as well as a series of scales tapping common factors (e.g., assessment of substance use and general functioning).

One more general comment - I do feel that you have too many measures/questionnaires for the participants to complete which may be quite burdensome. I know this is probably part of your feasibility assessment but I do wonder how necessary some of them are e.g. mental health

We agree there are many measures and it was part of the assessment to determine completeness. Additional text has been inserted “The suitability and acceptability of outcome measures will be assessed to determine the feasibility of including them in a full trial. Researchers’ perceptions of participants’ understanding (e.g. of language and meaning of questions) and acceptability (e.g. if participant refuses to answer or gets annoyed/frustrated or asks to end the interview) will be
recorded for each outcome measure using a pre-determined rating scale (1-lowest rating to 3-highest rating for understanding and acceptability).