**Supplementary material 1 – CONSERVE-CONSORT Checklist**

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| --- | --- | --- | --- | --- | --- |
| CONSERVE-CONSORT Extension: | | | | | |
| Item | Item Title | Description | | | Page No. |
| I. | Extenuating Circumstances | The COVID-19 pandemic and related restrictions significantly affected the delivery of the EASE Feasibility study. | | |  |
| II. | Important Modifications | 1. The modifications made were important as the study was trialling a novel psychological intervention with a vulnerable population. The study team needed to ensure the safety of the participants in terms of their physical health i.e., not putting them at risk of catching COVID-19, and also to support their mental health during a troubling time. Research staff were also required to work within the bounds of the rules set by the NHS at the time. | | |  |
| 1. Recruitment impact: due to COVID-19 restrictions, recruitment to the study was significantly affected. To mitigate infection risk, recruitment was paused from March 2020 until July 2020.   Intervention impact: Ten participants were receiving EMDRp and TAU at in March 2020, these sessions had to be suspended until July 2020, while the therapists and study team arranged to move the therapy to remote methods and gained research governance approvals from the relevant research authorities. Eight participants managed to successfully resume the therapy by remote means from July 2020 onwards. An extension to the therapy window was granted to mitigate the lost therapy time, but follow-up assessments were continued as per the original schedule. All further participants recruited after July 2020 who were allocated to the intervention arm were then offered therapy by remote methods.  Assessments and follow-up impact: Due to lock down restrictions these had to be moved to remote methods.  Funding impact: Due to the delay in recruitment and impact of moving the intervention and assessments to remove methods a funding extension was requested and granted by the Funder. | | | (see below) |
| 1. The study was extended by 6 months (. | | |  |
| III. | Responsible Parties | The study sponsor, research team, the trial Funder (NIHR) and Trial Steering Committee. | | |  |
| IV. | Interim data | N/A | | |  |
| CONSORT Number and Item | | For each row, if important modifications occurred check “direct impact” and/or “mitigating strategy” and describe the changes in the trial manuscript or supplement. Check “no change” for items that are unaffected in the extenuating circumstance. | | | Page No. |
| No Change | Impact\* | Mitigating Strategy\*\* |
| 1 | Title and abstract | ü |  |  | - |
| 2 | Introduction | ü |  |  | - |
| 3 | Methods: Trial Design | ü |  |  | - |
| 4 | Methods: Participants | ü |  |  | - |
| 5 | Methods: Interventions |  | ü | ü | 6, 11 |
| 6 | Methods: Outcomes | ü |  |  | - |
| 7 | Methods: Sample Size | ü |  |  | - |
| 8-10 | Methods: Randomisation | ü |  |  | - |
| 11 | Methods: Blinding | ü |  |  | - |
| 12 | Methods: Statistical methods | ü |  |  | - |
| 13 | Results: Participant flow |  | ü | ü | 10 |
| 14 | Results: Recruitment |  | ü | ü | 10-11 |
| 15 | Results: Baseline data | ü |  |  | - |
| 16 | Results: Numbers analysed | ü |  |  | - |
| 17 | Results: Outcomes and estimation | ü |  |  | - |
| 18 | Results: Ancillary analyses | ü |  |  | - |
| 19 | Results: Harms | ü |  |  | - |
| 20 | Discussion: Limitations |  | ü | ü | 14 |
| 21 | Discussion: Generalisability | ü |  |  | - |
| 23 | Other information: Registration | ü |  |  | - |
| 24 | Other information: Protocol | ü |  |  | - |
| 25 | Other information: Funding |  |  | ü | Funding extended |
| \*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder.  \*\*Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial. | | | | | |

**Supplementary Material 2 - Feasibility Outcomes and Feasibility Thresholds Considered in the feasibility RCT as reported in Varese *et al*., (2020)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
| **Criterion** | **Critical feasibility**  **outcome** | **Other feasibility and acceptability data**  **relevant to the criterion** |  | **Proposed thresholds on critical outcome** |
| 1. **Recruitment rate** | * Number of participants consented into the trial and randomised | * Number of referrals per month * Source of recruitment * Number of participants contacted, * number of participants assessed for eligibility * Reasons for non-eligibility or withdrawal of interest |  | Feasibility will be demonstrated where an average of at least 3 participants are recruited and randomised per month  If at least 2 participants are recruited per month, then a future trial will be feasible but additional strategies must be identified to support recruitment (e.g. informed by other feasibility data relevant to this criterion)  If an average of 1 participant is recruited per month over the recruitment period (<20 participants), feasibility within the current design will not be demonstrated |
| 1. **Therapy engagement** | * % who drop-out of therapy / % who did not receive treatment allocated | * Session record forms for each therapy session * Number of therapy sessions attended * Qualitative interviews with SU participants |  | Feasibility will be demonstrated if at least 70% of the participants in the intervention arm completed at least 8 out of the 16 sessions of EMDRp  If 50-70% of participants in the intervention arm complete at least 8 out of the 16 sessions of EMDRp  If less than 50% of participants in the intervention arm complete at least 8 out of 16 sessions of EMDRp |
| 1. **Assessment retention** | * % of participants who are lost to follow-up at end-of-treatment and follow-up assessment points | * Reasons for withdrawal from the study * Qualitative interviews with SU participants |  | If at least 70% of participants are retained and the end-of-treatment and follow-up assessments, feasibility will be demonstrated  If 30-70% of participants are retained at the end-of-treatment and follow-up assessments, a future trial will be feasible if strategies to overcome barriers are identified (e.g. via other data relevant to this criterion)  If less than 30% of participants are retained at the end-of-treatment and follow-up assessments, feasibility within the current design will not be demonstrated |
| 1. **Therapy fidelity** | * Adherence ratings from therapy tapes | * Session record form for each therapy session (including reasons for deviation from protocol) |  | Feasibility will be demonstrated if over 80% of rated therapy tapes will be rated as acceptable  If 50-80% of rated therapy tapes will be rated as acceptable, a future trial will be feasible if strategies to overcome identified barriers (e.g. exploring the reasons for deviation from protocol recorded in the therapist checklists)  If less than 50% of rated therapy tapes will be rates as acceptable, feasibility within the current design will not be demonstrated |
| *Note.* Key: Green = Continue to main study without modifications - feasible as it is; Amber = Continue but modify protocol – the future definitive trial is feasible with modifications. Red = Stop – future definitive trial is not feasible. | | | | |

**Supplementary material 3 – PANSS and PSYRATS scoring breakdown, as per factor solutions reported by Shafer & Dazzi (2019) and Woodward *et al.* (2014)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | EMDRp + TAU | | | TAU | | |  |  |  |
|  | Mean | SD | missing | Mean | SD | missing | Mean diff. | 80% CI | Cohen’s d |
| **PANSS** |  |  |  |  |  |  |  |  |  |
| **Positive** |  |  |  |  |  |  |  |  |  |
| Baseline | 16.0 | 3.7 | 0 | 15.5 | 3.5 | 0 |  |  |  |
| 6 Month | 13.2 | 4.7 | 1 | 14.2 | 4.1 | 0 | -1.0 | (-2.8, 0.7) | -0.2 |
| 12 Month | 11.6 | 5.5 | 1 | 12.5 | 3.5 | 1 | -1.0 | (-2.9, 1.0) | -0.2 |
| **Negative** |  |  |  |  |  |  |  |  |  |
| Baseline | 15.6 | 4.7 | 0 | 16.6 | 6.8 | 0 |  |  |  |
| 6 Month | 14.3 | 5.3 | 1 | 15.6 | 6.3 | 0 | -1.3 | (-3.6, 1.0) | -0.2 |
| 12 Month | 11.9 | 5.0 | 1 | 12.5 | 4.7 | 1 | -0.6 | (-2.6, 1.4) | -0.1 |
| **Cognitive** |  |  |  |  |  |  |  |  |  |
| Baseline | 12.8 | 3.6 | 0 | 13.5 | 3.8 | 0 |  |  |  |
| 6 Month | 11.4 | 3.0 | 1 | 13.3 | 3.7 | 0 | -1.9 | (-3.2, -0.6) | -0.6 |
| 12 Month | 10.4 | 3.7 | 1 | 11.0 | 1.6 | 1 | -0.6 | (-1.8, 0.6) | -0.2 |
| **Affective** |  |  |  |  |  |  |  |  |  |
| Baseline | 18.1 | 3.6 | 0 | 17.4 | 5.4 | 0 |  |  |  |
| 6 Month | 13.3 | 5.2 | 1 | 16.6 | 5.0 | 0 | -3.3 | (-5.3, -1.3) | -0.6 |
| 12 Month | 12.6 | 5.0 | 1 | 14.4 | 4.6 | 1 | -1.8 | (-3.7, 0.2) | -0.4 |
| **Excitative** |  |  |  |  |  |  |  |  |  |
| Baseline | 4.3 | 1.0 | 0 | 4.9 | 1.9 | 0 |  |  |  |
| 6 Month | 4.3 | 0.9 | 1 | 4.5 | 1.0 | 0 | -0.2 | (-0.5, 0.2) | -0.2 |
| 12 Month | 4.1 | 0.5 | 1 | 4.0 | 0.0 | 1 | 0.1 | (0.0, 0.3) | 0.4 |
| **PSYRATS-AH** |  |  |  |  |  |  |  |  |  |
| **H-DIS** |  |  |  |  |  |  |  |  |  |
| Baseline | 9.3 | 8.1 | 0 | 8.1 | 8.9 | 0 |  |  |  |
| 6 Month | 6.8 | 8.1 | 1 | 8.3 | 7.6 | 1 | -1.5 | (-4.6, 1.7) | -0.2 |
| 12 Month | 7.6 | 7.5 | 1 | 6.8 | 7.8 | 2 | 0.8 | (-2.4, 4.0) | 0.1 |
| **H-FRQ** |  |  |  |  |  |  |  |  |  |
| Baseline | 4.6 | 3.9 | 0 | 3.9 | 4.2 | 0 |  |  |  |
| 6 Month | 3.1 | 3.8 | 1 | 4.1 | 3.9 | 1 | -1.0 | (-2.5, 0.6) | -0.3 |
| 12 Month | 3.8 | 4.0 | 1 | 2.9 | 3.4 | 2 | 0.9 | (-0.7, 2.4) | 0.2 |
| **H-ATT** |  |  |  |  |  |  |  |  |  |
| Baseline | 3.1 | 2.6 | 0 | 2.6 | 2.7 | 0 |  |  |  |
| 6 Month | 2.1 | 2.5 | 1 | 3.2 | 2.9 | 1 | -1.1 | (-2.2, -0.1) | -0.4 |
| 12 Month | 2.9 | 2.9 | 1 | 2.7 | 2.9 | 2 | 0.2 | (-1.0, 1.4) | 0.1 |
| **H-LDN** |  |  |  |  |  |  |  |  |  |
| Baseline | 1.6 | 1.6 | 0 | 1.6 | 1.7 | 0 |  |  |  |
| 6 Month | 1.5 | 1.7 | 1 | 1.4 | 1.5 | 1 | 0.0 | (-0.6, 0.7) | 0.0 |
| 12 Month | 1.7 | 1.6 | 1 | 0.8 | 1.0 | 2 | 0.9 | (0.3, 1.5) | 0.6 |
| **PSYRATS-D** |  |  |  |  |  |  |  |  |  |
| **D-DIS** |  |  |  |  |  |  |  |  |  |
| Baseline | 6.1 | 2.3 | 0 | 4.7 | 3.1 | 0 |  |  |  |
| 6 Month | 3.7 | 3.3 | 2 | 3.7 | 3.4 | 0 | 0.0 | (-1.3, 1.3) | 0.0 |
| 12 Month | 2.4 | 3.2 | 2 | 3.1 | 3.4 | 2 | -0.7 | (-2.1, 0.7) | -0.2 |
| **D-FRQ** |  |  |  |  |  |  |  |  |  |
| Baseline | 9.7 | 2.9 | 0 | 8.9 | 4.1 | 0 |  |  |  |
| 6 Month | 6.8 | 4.6 | 1 | 7.2 | 4.6 | 0 | -0.4 | (-2.2, 1.4) | -0.1 |
| 12 Month | 4.6 | 5.4 | 2 | 4.9 | 4.9 | 1 | -0.3 | (-2.5, 1.9) | -0.1 |
| **GPRS** |  |  |  |  |  |  |  |  |  |
| **Social reference** |  |  |  |  |  |  |  |  |  |
| Baseline | 47.2 | 15.8 | 0 | 43.5 | 19.9 | 0 |  |  |  |
| 6 Month | 33.7 | 14.8 | 4 | 36.8 | 11.2 | 2 | -3.1 | (-8.6, 2.5) | -0.2 |
| 12 Month | 31.9 | 15.9 | 2 | 30.7 | 10.6 | 0 | 1.3 | (-4.3, 6.8) | 0.1 |
| **Persecution** |  |  |  |  |  |  |  |  |  |
| Baseline | 43.8 | 19.8 | 0 | 40.4 | 20.7 | 0 |  |  |  |
| 6 Month | 31.3 | 15.1 | 4 | 34.4 | 12.4 | 2 | -3.2 | (-9.0, 2.7) | -0.2 |
| 12 Month | 29.5 | 16.8 | 2 | 29.7 | 15.7 | 0 | -0.2 | (-6.9, 6.5) | 0.0 |