
















Supplementary Table 1. Approved trial monitoring and progression criteria to a future definitive trial

Criterion	Critical feasibility outcome	Other feasibility and acceptability data relevant to the criterion		Proposed thresholds on critical outcome
1) <b>Recruitment</b>	<ul style="list-style-type: none"> <li>Number of participants consented into the trial and randomised</li> </ul>	<ul style="list-style-type: none"> <li>Number of referrals per month</li> <li>Source of recruitment</li> <li>Number of participants eligible,</li> <li>Number of participants referred</li> <li>Reasons for non-eligibility or withdrawal of interest</li> </ul>	  	<p>Feasibility will be demonstrated where an average of least 7.84 participants are recruited and randomised per month (80% of recruitment target met).</p> <p>If at least 5.88 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) (60-80% of recruitment target met).</p> <p>If an average of under 5.88 participant is recruited per month over the recruitment period, feasibility within the current design will not be demonstrated (under 60% of recruitment target met).</p>
2) <b>Therapy engagement</b>	<ul style="list-style-type: none"> <li>% who drop-out of therapy</li> </ul>	<ul style="list-style-type: none"> <li>Session record forms for each therapy session</li> <li>Number of therapy sessions attended</li> <li>Qualitative interviews with SU participants</li> <li>Therapy satisfaction scores</li> </ul>	  	<p>Feasibility will be demonstrated if at least 80% of the participants in the intervention arm completed at least 4 out of the 6-8 sessions of MUSE.</p> <p>If 60-80% of participants in the intervention arm complete at least 4 out of the 6-8 sessions of MUSE.</p> <p>If less than 60% of participants in the intervention arm complete at least 4 out of the 6-8 sessions of MUSE.</p>
3) <b>Assessment retention</b>	<ul style="list-style-type: none"> <li>% of participants who are lost to follow-up at primary assessment endpoint (12weeks post randomisation)</li> </ul>	<ul style="list-style-type: none"> <li>Reasons for withdrawal from the study</li> <li>Qualitative interviews with SU participants</li> <li>Data completion</li> </ul>	  	<p>If at least 70% of participants complete primary outcome measure at primary assessment endpoint, feasibility will be demonstrated.</p> <p>If 50-70% of participants complete primary outcome measure at primary assessment endpoint, a future trial will be feasible if strategies to overcome barriers are identified (e.g. via other data relevant to this).</p> <p>If less than 50% of participants complete primary outcome measure at primary assessment endpoint, feasibility within the current design will not be demonstrated.</p>
4) <b>Therapy fidelity</b>	<ul style="list-style-type: none"> <li>Adherence ratings from therapy tapes</li> </ul>	<ul style="list-style-type: none"> <li>Session record form for each therapy session (including reasons for deviation from protocol)</li> </ul>	  	<p>Feasibility will be demonstrated if over 80% of rated therapy tapes are rated as acceptable.</p> <p>If 50-80% of rated therapy tapes are rated as acceptable, a future trial will be feasible if strategies to overcome barriers are identified</p> <p>If less than 50% of rated therapy tapes will be rates as acceptable, feasibility within the current design will not be demonstrated.</p>
5) <b>Safety</b>	<ul style="list-style-type: none"> <li>Number of related SAEs</li> </ul>	<ul style="list-style-type: none"> <li>Increased number of AEs in Intervention condition</li> </ul>	  	<p>0-1 Related SAEs in the Intervention arm.</p> <p>2 Related SAEs in the Intervention arm.</p> <p>3+ Related SAEs in the Intervention arm.</p>

