

Pilot and Feasibility Studies

Group music therapy with songwriting for adult patients with long-term depression (SYNCHRONY study): A feasibility and acceptability study of the intervention and parallel randomised controlled trial design with wait-list control and nested process evaluation

--Manuscript Draft--

Manuscript Number:	PAFS-D-22-00201R2	
Full Title:	Group music therapy with songwriting for adult patients with long-term depression (SYNCHRONY study): A feasibility and acceptability study of the intervention and parallel randomised controlled trial design with wait-list control and nested process evaluation	
Article Type:	Research	
Funding Information:	Research for Patient Benefit Programme (PB-PG-1014-35053)	Dr Catherine Elizabeth Carr
Abstract:	<p>Background: Despite effective treatments, one fifth of patients develop chronic depression. Music therapy may offer a different approach. This study aimed to assess feasibility and acceptability of a music therapy intervention and trial methodology.</p> <p>Methods: A parallel two-arm randomised controlled trial with wait-list control, mixed feasibility/acceptability measures and nested process evaluation. Adults with long-term depression (symptom duration >1 year) were recruited from community mental health services and computer randomised to 42 sessions of group music therapy with songwriting three times per week or wait-list control. Depression, social functioning, distress, quality of life, satisfaction and service use were assessed by blinded researchers at enrolment, one week, three and six months post-therapy. Outcomes were analysed descriptively, controlling for baseline covariates. Recruitment (number eligible, participation and retention rates) and intervention (fidelity, adherence) feasibility were assessed using predefined stop-go criteria. Attendance, adverse events, mood, relationship satisfaction and semi-structured interviews were analysed in a nested process evaluation.</p> <p>Results: Recruitment processes were feasible with 421 eligible, 12.7% participation and 60% (18/30) retention. Thirty participants were randomised to intervention (N=20) and control (N=10). Session attendance was low (mean 10.5) with four withdrawals. Music therapist adherence was good but changes to session frequency were suggested. Outcomes were available for 10/20 treatment and 9/10 wait-list participants. Depression increased in both arms post-therapy. Treatment depression scores fell below baseline 3 and 6 months post-therapy indicating improvement. Wait-list depression scores increased from baseline 3 and 6 months post-therapy. At three months, the treatment arm improved from baseline on all measures except satisfaction and functioning. At six months, quality of life, distress and functioning improved with reduction in health service contacts. High-attending participants improved more than low-attending. Seven adverse events (one serious) were reported.</p> <p>Limitations: As this was a feasibility study, clinical outcomes should be interpreted cautiously.</p> <p>Conclusion: A randomised controlled trial of group music therapy using songwriting is feasible with inclusion criteria and session frequency modifications, but further intervention development is required.</p> <p>Trial Registration: ISRCTN18164037 on 26.09.2016.</p> <p>Funding: National Institute for Health Research, Research for Patient Benefit (PB-PG1014-35053)</p>	
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Response to Reviewers:	Thank you for your responses and decision to accept on the basis of one minor revision. As requested by the reviewer, we have removed the duplicate sentences in the abstract/results section (page 2, line 46-7: "High-attending participants improved more than low-attending. Seven adverse events (one serious) were reported."). Yours sincerely, Catherine Carr, on behalf of the authors
Suggested Reviewers:	Felicity Baker Felicity.Baker@unimelb.edu.au Leading authority on songwriting in music therapy Katherine Myers-Coffman kmyers-coffman@molloy.edu Lead author on a feasibility study of songwriting for bereaved adolescents.
Additional Information:	
Question	Response
<p>Declarations</p> <p>Have you included a 'Declarations' section in your manuscript including all of the subheadings listed below and the relevant information under each?</p> <ul style="list-style-type: none"> Ethics approval and consent to participate Consent for publication Availability of data and material Competing interests Funding Authors' contributions Acknowledgements <p>Click here for information on what should be included under each heading.</p> <p>Please use the 'Contact Us' link above if you require further assistance</p>	I confirm I have provided a complete 'Declarations' section in my manuscript
<p>Is this study a clinical trial?</p> <p>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related</p>	Yes

<p>interventions to evaluate the effects on health outcomes'.</i></p>	
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<i>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</i>"</p>	<p>18164037</p>
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<i>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</i>"</p>	<p>https://www.isrctn.com/ISRCTN18164037</p>
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<i>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</i>"</p>	<p>09-26-2016</p>
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<p>or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</i>"</p>	
<p>Was your trial registered before the first participant was enrolled? (i.e. prospectively registered)
&nbsp;as follow-up to "Is this study a clinical trial?<hr><i>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</i>"</p>	<p>Yes</p>
<p>Within your manuscript, have you also included details of your trial registration at the end of your abstract?Name of the registryTrial registration numberDate of registrationURL of trial registry record<p><i>Example: Trial registration: ISRCTN, ISRCTN12345678. Registered 28 September 2014, http://www.isrctn.com/ISRCTN12345678</i>
&nbsp;as follow-up to "Was your trial registered before the first participant was enrolled? (i.e. prospectively registered)"</p>	<p>I confirm I have provided trial registration details at the end of the abstract</p>

Dear Caitlin and reviewers,

PAFS-D-22-00201-[EMID:8fd49e20a468d170] – Feasibility and acceptability of group music therapy with songwriting for long-term depression (SYNCHRONY study): A randomised controlled trial with nested process evaluation and wait-list control

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Yours sincerely,

Catherine Carr, on behalf of the authors

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1 Group music therapy with songwriting for adult patients with long-term depression (SYNCHRONY
2 study): A feasibility and acceptability study of the intervention and parallel randomised controlled
3 trial design with wait-list control and nested process evaluation

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23 Abstract:

24 Background: Despite effective treatments, one fifth of patients develop chronic depression. Music
25 therapy may offer a different approach. This study aimed to assess feasibility and acceptability of a
26 music therapy intervention and trial methodology.

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Conclusion: A randomised controlled trial of group music therapy using songwriting is feasible with inclusion criteria and session frequency modifications, but further intervention development is required.

Trial Registration: ISRCTN18164037 on 26.09.2016.

Funding: National Institute for Health Research, Research for Patient Benefit (PB-PG1014-35053)

Key words: Chronic depression; Long-term depression; Group Music Therapy; Songwriting;

Randomised controlled trial; Feasibility

Key messages regarding feasibility

- What uncertainties existed regarding the feasibility?

Music therapy is a promising intervention for depression but has not been tested in a group songwriting format for long-term depression. We were also uncertain about the numbers that would meet our definition of long-term depression and how best to identify and recruit them to our study.

- What are the key feasibility findings?

The study methods were feasible and acceptable to participants and we were able to recruit sufficient numbers within the timeframe required. Group attendance was low, with a high proportion not attending a single session, and initial high attrition. Inclusion criteria may require a more stringent assessment of depression severity and this may aid identification of participants more likely to attend the intervention. Outcomes suggested a worsening of symptoms post-intervention in both arms before improvements three months later. The intervention requires further modification in terms of frequency, location, music therapist technological support and support for group members once the groups come to an end.

- What are the implications of the feasibility findings for the design of the main study?

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70 Recruitment is most successful from secondary mental health services, with options for patient self-
71 referrals. Further development of the intervention and piloting to determine the primary endpoint
72 are required before a larger trial is implemented.

73 Background

74 The global burden of depression is well-recognised: Despite many effective treatments, around one in
75 five diagnosed with an acute depressive disorder develop chronic depression [1]. The severity and
76 course of symptoms vary from 'milder' symptoms of dysthymia to chronic major depression [2]. For
77 this specific patient group, median durations are estimated between five to twenty years [3,4] with
78 associated increased health care costs through greater use of services and rates of hospitalisation [5-
79 7]. Known risk factors include younger age of onset, childhood adversity and abuse [8-18], family
80 history of mood disorder and problems within the social environment (such as low social integration,
81 support and negative social interaction) [3].

82 Chronic or persistent depression is defined by symptoms lasting 2 or more years. However, durations
83 of 1 year or longer are still both clinically relevant (in terms of distress) and may be indicative of a
84 chronic course [8, 19]. Around 40% of chronically depressed patients fulfil the criteria for treatment
85 resistance, which can be identified as soon as 6 months post-diagnosis (or after two trials of
86 antidepressant drugs)[20]. This suggests that symptoms enduring for one year or longer are both an
87 indicator of future chronicity and a need for further intervention. For the purposes of this study, we
88 use the term 'long-term depression' to define patients with symptoms of depression that have lasted
89 one year or longer.

90 Treatment of long-term depression is particularly difficult: Frequent relapses can lead to pessimism
91 and demoralisation of both patient and professional [4] leading in turn, to lack of compliance or 'giving
92 up' on treatment. There is evidence for both pharmacotherapy [21-2] and psychotherapy [23] as
93 effective treatments. These effects appear to be maximised when used in combination [24] although
94 around 18 sessions of psychotherapy may be necessary in order to see clinical effects [25]. A later

1 95 review found limited evidence for their use in combination [26] but suggested psychotherapy might
2 96 have a continued role in promoting and maintaining treatment adherence, given patient preferences
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4 97 are often for psychotherapy over medication and achieving wider clinical benefits (such as improved
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6 98 coping strategies and quality of life). As a result, clinical guidelines recommend combined treatment
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9 99 with a personalised approach [9].

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12 100 There is good evidence for psychotherapy interventions that target interpersonal problems (such as
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14 101 the cognitive behavioural analysis system of psychotherapy (CBASP) and interpersonal psychotherapy
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16 102 (IPT) [27]. Similarly, long-term psychoanalytic psychotherapy has been shown to improve long-term
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19 103 outcomes in treatment resistant depression [28]. Given the social environment is a known risk factor
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21 104 for this population [3,29], group formats may promote social integration, interaction, provide
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24 105 emotional and social support and offer potential cost-effectiveness.

25 26 27 106 Group music therapy

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30 107 Music therapy is a complex intervention provided by music therapists that uses a range of expressive
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32 108 and receptive musical activities, verbal reflection and the relationships developed through this to
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34 109 improve health [30]. Within the United Kingdom (UK), music therapists are regulated by the Health
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37 110 and Care Professions Council (HCPC) and must have completed accredited Masters level training.
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39 111 Within the UK, practice most often uses a combination of active musical improvisation and verbal
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42 112 reflection within sessions, which can take an individual or group format.

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45 113 There is promising evidence for the effectiveness of music therapy in treating depression [31] and it
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47 114 may benefit this population for several reasons. As an intervention, it may be appealing and
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50 115 motivating given the different focus on use of the art form and thus encourage attendance and
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52 116 engagement [32-3]. The experience of making music provides a very different therapeutic encounter;
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54 117 music has an immediate impact (often positive) on mood [34] and within groups (especially singing),
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57 118 can promote social bonding [35]. A positive experience within a community-based group may then
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59 119 place the person in contact with their musical and psychological 'resources' [36], which – linking to

120 wider theories of recovery in mental illness- may provide opportunities to build inner resources of
121 coping, resilience and promote hope [37-8].

122 Through co-created musical improvisation it is possible to give sound to, experience, express and
123 transform feeling states, form relationships and communicate with others without words. These
124 experiences may promote opportunities for more positive social interactions than those experienced
125 verbally. The musical attunement facilitated by music therapists when improvising may help patients
126 to experience nonverbal social contact, closeness, emotional containment and address feelings of
127 social isolation [39]. This process is implicated in building initial therapeutic trust, which is an
128 important factor for this patient group [40]. Notably, a randomised controlled trial of individual
129 psychodynamic improvisational music therapy for depression [41] found additional benefits on
130 alexithemia, suggesting that musical improvisation assisted patients in naming internal feeling states.

131 A further music therapy trial used group songwriting for patients with severe mental illness and
132 demonstrated improved quality of life [33]. Creating bespoke songs as a group has the potential for
133 participants to begin to find ways of putting their internal experiences into words and to have this
134 supported through group discussion and music making [42].

135 Clinical benefits are associated with the number of sessions received. One meta-analysis [43]
136 suggested around 4 sessions would be required for a small effect on depressive symptoms, 10 for a
137 medium effect and 16 for a large effect. The impact of session frequency and duration is less clear.
138 Within the UK, sessions are often offered on a weekly basis. However, internationally, frequency can
139 range from 1-6 sessions per week [43].

140 In designing the intervention for this study, we consulted with patient and carer groups, who
141 suggested that singing would be a more accessible and acceptable way of making music than
142 instrumental improvisation. They also emphasised the importance of having an 'end product' in
143 promoting self-esteem, self-efficacy and achievement in their recovery. We therefore took a group
144 songwriting protocol [33] as our starting point and through focus groups with music therapists and

1
2 145 clinical psychologists and interviews with patients with depression, incorporated principles from
3
4 146 psychodynamic improvisational music therapy [40] and resource-oriented music therapy [36, 44].

5 147 By offering a regular intensive group format (3 sessions per week), we hypothesised that patients
6
7 148 would have opportunities to make music together thus providing opportunities to build trust and bond
8
9 149 with others, improve mood and build relationships. We hypothesised this could lead to a range of
10
11 150 relevant outcomes such as short-term reduction in psychological distress and improved social
12
13 151 functioning. The above could also contribute to improved self-esteem and self-efficacy and taken as a
14
15 152 whole, a reduction in depression symptoms. Secondary impacts of a reduction in depression were
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17 153 hypothesised to be improved satisfaction with services, a reduced impact of depression upon work
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19 154 and life and improved quality of life.
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25 155 Current evidence suggests group music therapy may offer an alternative and potentially clinically
26
27 156 beneficial treatment for long-term depression. However, the intervention has not been specified or
28
29 157 tested specifically for this population using a group and songwriting format within a UK National
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31 158 Health Service (NHS). Whilst music therapy is commonly provided in NHS mental health care, provision
32
33 159 is often to diagnostically heterogeneous groups. Similarly, whilst songwriting is a recognised music
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35 160 therapy technique, it is less frequently used in the UK. It was therefore important to assess whether
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37 161 the intervention was delivered as described and its general acceptability to both patients and music
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39 162 therapists.
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45 163 In terms of the research design, it was important to assess our proposed methods for identifying,
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47 164 recruiting and retaining participants. In particular, we were unsure of the numbers who might meet
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49 165 our definition of 'long-term' depression, where they might be identified within services, nor of the
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51 166 best ways to identify them. Running the study on a small scale enabled us to examine how feasible
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53 167 our proposed processes were and to estimate the resources and most effective approaches required
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55 168 [45]. We were similarly unsure which measures might be most appropriate in terms of acceptability
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169 of completion, the variability of outcomes and what level of clustering might be expected within
170 groups.

171 Aims and objectives

172 This study aimed to pilot a group songwriting music therapy intervention for patients with long-term
173 depression and assess the feasibility and acceptability both of the intervention and of conducting a
174 larger randomised controlled trial. In addition, the study sought to gather descriptive information on
175 health service use in order to inform a future health economic evaluation.

176 Objectives

177 a) Feasibility and acceptability of research methodology

178 1. Assess the feasibility of recruitment processes

179 2. Identify the number of eligible participants, participation and retention rates

180 3. Assess the researcher time required

181 4. Assess the appropriateness of outcome measures, including providing data on the variability of
182 outcome, an estimate of the control group mean and the intra-cluster correlation coefficient.

183 5. Assess the acceptability of the research methodology to professionals and patients

184 b) Feasibility and acceptability of intervention

185 6. Assess the intervention in terms of testing use of components, measuring adherence and estimating
186 the likely intervention effect.

187 c) Assessment of service use for health economic evaluation

188 7. Assess the services received by participants in preparation for a health economic evaluation.

189 Methods

190 A parallel two-arm randomised controlled feasibility trial with mixed methods evaluation. Participants
191 were assessed at the point of enrolment (baseline), the week post-intervention, 3 and 6 months post-
192 intervention. Shopping vouchers of £10 were offered at baseline and for subsequent assessments for
193 treatment participants. Wait-list participants were paid £15 per follow-up to acknowledge the delay
194 to treatment. The study was given favourable ethical opinion from the Health Research Authority
195 (IRAS project ID: 198964, REC reference:16/WA/0248) and the study protocol was published with open
196 access in March 2017 [46].

197 Four amendments were made during the study. We amended the patient information sheet and
198 consent form to include the possibility of payment for travel to therapy sessions where patients did
199 not hold a 'freedom pass'; a substantial amendment was made to move the post-test assessment
200 point from one month post-intervention to immediately at the intervention end to maximise follow-
201 up rates and capture any immediate treatment effects; we clarified payment of £10 for participation
202 in qualitative interviews to ensure consistency with previous assessments; finally, prior to
203 commencing music therapy for the wait-list group, we opened up two spaces to patients outside the
204 study to ensure a critical mass of group members could be maintained.

205 Eligibility criteria

206 As this was a feasibility trial, our inclusion criteria were as broad as possible. Participants were eligible
207 if they had a confirmed diagnosis in the International Classification of Diseases and Related Health
208 Problems (version 10) (ICD10), of depression (ICD10 F31-39), including post-schizophrenic depression
209 (ICD10 F20.4) and prolonged depressive reaction (ICD10 F43.21), had received pharmacological
210 and/or psychological treatment for 12 months or longer, were aged 18 years or above and had
211 capacity to give written informed consent. We excluded any diagnosis of organic mental disorder
212 (ICD10 F00-09), bipolar affective disorder if current manic episode (ICD10 F30, F31.0, F31.2, F31.6,
213 F31.7-4), if they lacked capacity to give informed consent or were at risk of suicide necessitating

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2 214 hospitalisation. Previous receipt of music therapy or other psychological therapies did not form part
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4 215 of the eligibility criteria, but were recorded as part of baseline clinical characteristics.

5 216 Setting and participant identification

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8 217 The study took place in East London NHS Foundation Trust. Research assistants recruited participants
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10 218 via: a) primary care, via General Practice (GP) surgeries, b) secondary care via improving access to
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12 219 psychological therapies (IAPT) services and community mental health care teams. GP surgeries were
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14 220 invited to sign up to act as recruiting centres. A practice staff member then sent letters of invitation
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16 221 to any potentially eligible patients. Within secondary care, caseloads were screened by a clinical
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18 222 studies officer who was part of the care team and potential participants were approached by the
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20 223 professional responsible for their care. An unexpected third means of recruitment was via patient self-
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22 224 referral through presentations about the study to patient and carer groups across the Trust. Where
23
24 225 patients expressed interest, permission was gained to contact their healthcare professional to check
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26 226 eligibility and then a meeting arranged to go through informed consent.
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33 227 Participant consent

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36 228 Recruitment lasted for 8 weeks between September and November 2016. Interested patients were
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38 229 provided with an information sheet and then met with a member of the research team to give written
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40 230 informed consent and complete baseline measures. To support retention, we aimed wherever
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42 231 possible for the researcher conducting baseline assessments to continue with that participant for all
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44 232 follow-up assessments.
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48 233 Intervention (Group music therapy with songwriting)

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51 234 <Insert table 1 here>
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54 235 The Synchrony group music therapy with songwriting intervention is summarised according to the
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56 236 Template for Intervention Description and Replication (TIDieR) checklist [47] in Table 1. A manual for
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58 237 the Synchrony group music therapy with songwriting intervention [Additional File 1], based on Grocke
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1 238 et al. [33] and informed by individual psychodynamic music therapy for depression [40] and resource-
2 239 oriented music therapy [36] was developed prior to the study taking place through focus groups with
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4 240 music therapists, psychologists and interviews with patients with depression. The manual was
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7 241 finalised through regular meetings with the music therapists providing the intervention and Heads of
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9 242 Arts Therapies.

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12 243 Adaptations to Grocke et al.'s intervention [33] included group members sharing pre-known songs in
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14 244 the early phases of the group; group improvisation after ice-breaker activities and before working on
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17 245 songs; and building time for the group to decide what they would like their end product to be (eg. a
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19 246 compact disc (CD) or a group performance). Unlike Grocke et al. [33] who used a recording studio at
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22 247 the end of therapy, recording took place during the music therapy sessions using GarageBand software
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24 248 [48] and formed a major part of the group process.

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27 249 Based on feedback from patient and carer groups, group music therapy took place in non-NHS
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30 250 premises in a community centre within one London borough. The centre offered facilities for
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32 251 additional social contact, such as a café and wider non-medical community groups. Sessions were
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34 252 provided three times per week over 14 weeks by two HCPC-registered music therapists. Sessions
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37 253 lasted 90 minutes and consisted of opening warm-up activities (such as passing an instrument),
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39 254 sharing current state (which, with permission, was written onto a flip chart for later lyric writing) and
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42 255 then moving into group improvisation. Music therapists transitioned into songwriting from this point,
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44 256 focusing on lyric creation, musical ideas or motifs and later recording. Opportunities were offered
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46 257 after each activity for verbal reflection. The last 15 minutes were dedicated to reviewing the session
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49 258 either through group discussion, or by playing music together.

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52 259 Wait-list control

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55 260 The wait-list control group received treatment as usual for the study duration, which involved either
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57 261 psychopharmacological medication, psychological therapy or a combination. At the end of the final
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60 262 follow-up assessment, a further songwriting music therapy group was offered to these participants.

263 Assessment measures

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3 264 The purpose of a feasibility study is to determine whether or not it is possible to proceed with a given
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5 265 intervention or research design before moving to a larger scale [49]. In order to do this, it is
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7 266 recommended to establish pre-defined stop-go criteria [49] to aid the decision of whether or not to
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10 267 proceed. While the criteria can vary from study to study, many take the format of a ‘traffic light’
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12 268 system to aid identification of thresholds where a criterion is feasible (‘green’), not feasible (‘red’) or
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14 269 potentially feasible with modifications (‘amber’). Our pre-defined stop-go criteria were published in
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17 270 the study protocol [46] and are summarised in Table 2.

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20 271 <Insert Table 2 here>

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23 272 a) Feasibility/acceptability of the research methodology (objectives 1-5)

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26 273 Feasibility of recruitment processes (objective 1) and identification of the number of eligible
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28 274 participants, participation and retention rates (objective 2) were assessed through descriptive analysis
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31 275 of recruitment and drop-out rates and qualitative end interviews with participants and referring staff.
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33 276 Researcher time (objective 3) was assessed through researchers keeping logs of contact, dates of visits
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36 277 and time taken throughout the study. Outcome measure appropriateness (objective 4) was assessed
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38 278 by examining descriptive statistics and missing data. For clinical outcomes, our proposed primary end-
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41 279 point was in the week following the intervention end (post-intervention), with secondary endpoints 3
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43 280 and 6 months post-intervention. Acceptability of the research methodology to participants and
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45 281 patients (objective 5) was assessed through thematic analysis of qualitative interviews at the end of
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47 282 intervention.

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54 284 b) Feasibility/acceptability of the intervention (objective 6)

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57 285 Feasibility/acceptability of the intervention (objective 6) was assessed through a nested process
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59 286 evaluation which aimed to understand a) how the intervention was delivered in practice (treatment

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287 fidelity analysis), b) Describe processes of attendance and hypothesised process factors of self-
288 reported depression, mood and group relationships from week to week and c) understand subjective
289 experiences and attributions for change of the intervention from the perspective of patients, music
290 therapists and referring staff. To assess treatment fidelity, music therapist self-reported adherence to
291 the manual each session and video analysis of 25% of sessions by independent raters (both music
292 therapists) was collected using the same adherence proforma. To examine attendance and
293 hypothesised process factors, group attendance, self-reported depression and weekly process
294 measures of mood and group relationships were collected. For subjective experiences and change
295 attributions, end of therapy interviews were conducted with patients and music therapists using the
296 Client Change Interview [50]. This was adapted for referring staff and music therapists to reflect on
297 changes observed in participants. Qualitative interviews were conducted by unblinded members of
298 the research team and clinical studies officers supporting the study. Finally, as part of good clinical
299 practice, adverse events were monitored throughout the study and were considered in relation to
300 intervention safety and potential adverse outcomes.

301 c) Health service use (objective 7)

302 Health service use data were collected by examining medical records for any hospitalisation and using
303 the Client Services Receipt Inventory at baseline, in the week following the intervention (post-
304 intervention), 3 and 6 months post-intervention.

305 Proposed primary symptom outcomes

306 Both observer-rated and self-report measures were used to assess depression symptoms.

307 *Montgomery-Åsberg Depression Rating Scale (MADRS) [51]*

308 The MADRS is an observer rated 10-item scale known to be sensitive to change with good predictive
309 validity for major depressive disorder [52]. Symptoms are rated from 0 (not present) to 6 (extreme
310 problems) and summed to form a total score (0-60). Research Assistants were trained in its use with

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311 the accompanying interview guide (SIGMA [53]) prior to assessments with high inter-rater reliability
312 (ICC=.995 (p<.001), 95% CI .987-.999). Estimates for the minimal clinically important difference (MCID)
313 range from a 1.6-1.9 change from baseline with remission cut-off at <9 points [54-5]. Bandelow et al.,
314 found scores ≤5 are symptom free remission, ≤11 remission and a decrease in 39% from baseline
315 corresponded to ‘much improved’ on the clinical global impressions scale [56-7].

316 *Beck Depression Inventory II (BDI-II) [58]*

317 The BDI-II is a widely used self-reported 21-item measure of depression with good internal
318 consistency, sensitivity to change and established cutoffs for minimal (raw score <13), mild (14-19),
319 moderate (20-28) and severe (29-63) depression [58]. Items are rated on a scale of 0 (no problems) to
320 3 (extreme problems), and summed to form a total score (0-63). The estimated MCID is estimated at
321 either a reduction of 5 points [59-60] or a 30% reduction in total score [61], 17.5% reduction in scores
322 for depressed patients, and 32% for those with a longer duration and non-response to antidepressants
323 [62].

324 Secondary and exploratory outcomes

325 *Brief Symptom Inventory (BSI) [63]*

326 The BSI is a widely used 53-item self-report measure of psychological distress with good internal
327 consistency and established outpatient norms in both United States and UK samples [63-4]. Symptoms
328 are rated on a Likert scale from 0 (not at all) to 4 (extremely). There are nine subscales for symptom
329 clusters (0-4) and three global indices of distress; global severity index, positive symptom distress
330 index and positive symptom total, of which global severity is used as a single summary measure.

331 *Rosenberg self-esteem scale (RSES) [65]*

332 The RSES is a widely used 10-item self-report measure of self-esteem. Items are rated on a 4-point
333 Likert scale from ‘strongly agree’ to ‘strongly disagree’. Four items are reverse scored, and item totals

334 are summed (0-40). The scale has good internal consistency (0.68-0.86) [66] and construct validity
335 [67].

336 *General Perceived Self-efficacy Scale (GPSES) [68]*

337 The GPSES is a 10-item self-report measure of personal agency, rated on a 4-point Likert scale from
338 'not at all true' to 'exactly true'. Item totals are summed (10-40). The scale has confirmed uni-
339 dimensionality and good internal consistency (0.82-0.93) [68].

340 *Client satisfaction questionnaire (CSQ) [69]*

341 The CSQ measures self-reported satisfaction with services, and is rated on an 8-item scale from 1
342 (dissatisfied) to 4 (very satisfied) and items summed (8-32). The scale is widely used in health
343 services research and has good internal consistency (0.83-0.93)[69].

344 *Work and social adjustment scale (WSAS) [70]*

345 The WSAS is a self-report 5-item scale that measures the degree to which work and social life are
346 impaired due to a health condition. Items are rated on an 8-point scale from 0 (not at all impaired) to
347 8 (very severely impaired). Item totals are summed (0-40). The scale has demonstrated internal
348 consistency (0.70 -0.94), and a test-retest correlation of 0.73 [70].

349 *Manchester Short Quality of Life scale (MANSA)[71]*

350 The MANSA is a 16-item self-report scale measuring satisfaction with different areas of life. Twelve
351 items are rated on a 7-point Likert scale ranging from 1 ('couldn't be worse') to 7 ('couldn't be better')
352 which are summed (12-84). Four items are dichotomous (yes/no) to indicate whether the person has
353 a close friend, saw a friend in the last week, were accused of a crime or were a victim of physical
354 violence. The scale has good internal consistency (0.74) and correlations of 0.83 and higher with the
355 longer Lancashire Quality of Life Profile [71].

356 *Life Skills Profile (LSP) [72]*

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357 The LSP is an observer rated 39-item profile, originally designed for patients with schizophrenia.
358 Various domains of social functioning are rated on a 4-point scale from no difficulty (4) to considerable
359 difficulty (1). Items are summed into five subscales: self-care, non-turbulence, social contact,
360 communication and responsibility and overall functioning score (39-154). Internal consistency ranges
361 from 0.67-0.88 and the scale demonstrated good sensitivity to change in community patients with
362 chronic mental illness within an assertive outreach service [73].

363 *Level of hospitalisation*

364 Psychiatric hospital admissions, length of stay and readmissions were recorded from medical records
365 for the purposes of this study.

366 *Client services receipt inventory (CSRI) [74]*

367 The CSRI was used to collect information on face-to-face professional contacts, use of day care
368 services, contact with police, medications, time off work/college and receipt of state benefits.

369 *Process measures*

370 Within the treatment arm, process measures of mood and group relationships were administered
371 once per week pre- and post session. In addition, the BDI-II was completed post-session in week 3, 6,
372 9 and 12 of the intervention to track any self-reported changes in depression during the intervention
373 period. Attendance was logged by the therapist at every session, and reasons for non-attendance
374 recorded. Finally, qualitative end of therapy interviews were completed with participants in both
375 treatment and wait-list groups. These interviews were optional for participants.

376 *Dispositional Mood Scale (DMS) [75-6]*

377 The DMS is a self-report scale consisting of 20 adjectives describing current internal states.
378 Adjectives are rated on a scale of 1 (very slightly or not at all) to 5 (extremely) and summed as four
379 subscales of positive energy, tiredness, negative activation and relaxation. A further two-factor

1
2 380 solution is possible: 'Pleasant-Activation, Unpleasant Deactivation' and 'Unpleasant activation,
3 381 Pleasant deactivation'. Internal consistency varies between α : 0.83 - 0.93 [75].
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5 382 *Relationship Satisfaction Scale (RSS) [77]*
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8 383 The RSS is a 7-item self-report scale assessing the quality of a relationship. Items are rated on a 7-
9 point Likert scale from 0 ('very dissatisfied') to 6 ('very satisfied') and summed to form an overall
10 384 satisfaction score. The scale has not been validated, but assessed domains of relevance to group
11 385 relationships (eg. communication and openness, conflict resolution, intimacy and closeness).
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13 386 relationships (eg. communication and openness, conflict resolution, intimacy and closeness).
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18 387 *Music therapy group attendance*
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21 388 Attendance was recorded by the music therapists every session on a pre-designed proforma,
22 including space to record reasons for non-attendance.
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24 389 including space to record reasons for non-attendance.
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27 390 *Experience of therapy and research incorporating adapted Client Change Interview [50]*
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30 391 A topic guide was pre-designed to enquire about experiences of both the therapy and taking part in
31 the study in qualitative interviews. For participants in the treatment arm, the Client Change
32 392 Interview [50] was used to explore helpful and hindering factors in therapy, changes experienced
33 during therapy and attributions for this.
34
35 393 Interview [50] was used to explore helpful and hindering factors in therapy, changes experienced
36 during therapy and attributions for this.
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38 394 during therapy and attributions for this.
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40 395 *Adverse events*
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43 396 Adverse events were recorded from the point of written informed consent to seven days post-
44 cessation of the study. Active monitoring commenced from the first point of attendance of group
45 397 music therapy to one week after the intervention finished. Expected adverse events were defined as:
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48 398 music therapy to one week after the intervention finished. Expected adverse events were defined as:
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- 52 • A participant exhibiting aggression (nonverbal or verbal behaviour)
 - 53 400 • A participant causing harm to another person
 - 54 401 • Disclosure of thoughts or plans which may place the individual or others at risk of harm.
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59 402 Serious adverse events that were defined for this study context included:
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- 403 • A participant making a suicide attempt
- 404 • A participant causing life threatening injury to another
- 405 • An event occurring during the course of the study which resulted in hospitalisation or
406 prolongation of existing hospitalisation related to their mental health.

407 Rationale for sample size

408 Papers considering sample size for feasibility studies suggest inclusion of upwards of 24-50
409 participants [78-80]. As the feasibility of our recruitment processes and sample were unknown, we
410 based our sample size around what was practicable to provide within the study timeframe. We aimed
411 to recruit 30 patients to participate in three groups of 10 patients in each. Participation rates in similar
412 studies were between 25-33% of eligible patients consenting [81-3]. A sample size of 30 would allow
413 us to estimate a participation rate of 25% to within 95% confidence interval of +/-15%. We estimated
414 1300 patients would be eligible within primary care (assuming one fifth of those with current
415 depression) and that each practice in the locality would therefore have around 20 with enduring
416 symptoms. Secondary care services reported around 1960 patients with a diagnosis of depression,
417 suggesting 392 would be potentially eligible for this study. Assuming a participation rate of 25% we
418 aimed to approach 128 patients, with the aim of recruiting 4 per week over 8-10 weeks.

419 Randomisation

420 To gain sufficient information regarding the intervention, we used an imbalanced design, randomising
421 20 participants to group music therapy and 10 to the wait-list control. We used simple block
422 randomisation once all 30 participants were recruited and baseline measures completed.
423 Randomisation was generated by a researcher independent to the study team, using the Experimental
424 Design Generator and Randomiser (EDGAR-II)[84]. One unblinded study team member and music
425 therapists were informed of the allocation, who then informed participants.

426 Blinding

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427 Researchers conducting assessments and the co-Chief Investigator (Priebe) were blinded to
428 participant allocation. Due to the trial design, participants, music therapists and the clinical teams
429 were not blinded to allocation. One Chief Investigator (Carr) and Clinical Studies Officers were
430 unblinded to enable communication with clinicians and administration of process measures.

431 To maintain blinding of researchers, it was explained to participants on allocation that it was important
432 not to reveal this to the researcher who had conducted their assessments. Participants were reminded
433 in every communication from researchers not to mention whether they had received music therapy
434 or not.

435 Analysis

436 For research methodology feasibility measures (objectives 1-4) we calculated screening, recruitment
437 and drop-out rates, distributions of baseline characteristics and all outcomes one week, 3 and 6
438 months post-intervention. Clinical outcomes were analysed as intention-to-treat, using mean scores
439 for each group and 95% confidence intervals. We then used a mixed linear model, adjusting for
440 baseline scores of the given outcome and any significant baseline characteristics. The intra-cluster
441 correlation coefficient was calculated for group clustering. Adverse events were categorised and
442 reported for each trial arm.

443 For intervention feasibility measures (objective 6), we explored using descriptive statistics, any
444 differences between compliant/non-compliant attenders, responders and non-responders.

445 Qualitative interviews were analysed in two stages. In the first stage, participants who had received
446 music therapy were analysed to explore their experiences of the intervention and any changes
447 (objective 6) using interpretative phenomenological analysis [85]. This enabled us to gain an in-depth
448 understanding of participants' experiences during the songwriting groups including the meaning
449 attributed by participants to their experiences. Further details of the analysis and findings are
450 published in full elsewhere [85]. In a second stage, given the larger number of interviews and
451 predefined format of research procedures, comments relating to acceptability and experiences of

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2 452 research procedures (objective 1) were analysed using deductive coding against each element of the
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4 453 research design and then grouped to form a basic thematic analysis [86]. For health service use
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6 454 (objective 7), hospitalisation and use of services were examined descriptively and compared between
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8 455 groups.
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10 456 Results

11 12 13 457 a) Feasibility and acceptability of research methodology (objectives 1-5)

14 15 16 458 Recruitment

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19 459 Flow of participants in the study are shown in the Consolidated Standards of Reporting Trials
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21 460 (CONSORT) diagram (Figure 1) and baseline characteristics in Table 3. A total of 421 patients were
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23 461 screened and 235 potentially eligible participants identified. Reasons for exclusion at this stage were
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25 462 not meeting the inclusion criteria (N=105), no clinician assent for contact (N=63), researchers unable
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27 463 to make contact (N=25) or participants being deemed too unwell to approach (N=13) or unsuitable by
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29 464 clinicians (N=5). Five were discharged from services before they could be approached. Of the 235
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31 465 participants approached, 83 expressed interest with a participation rate (from potentially eligible
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33 466 participants) of 12.7%. Forty-six declined while 146 were unable to contact or did not respond. One
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35 467 GP practice participant expressed interest but was too late to join the study, and one self-referred
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37 468 participant was too unwell to recruit within the study window. Whilst there were equivalent numbers
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39 469 of potentially eligible participants within GP and Community Mental Health settings, recruitment was
40
41 470 most successful via Community Mental Health teams (CMHT) and self-referral from public
42
43 471 engagement events. The recruitment target was achieved, with 30 participants providing informed
44
45 472 consent over an eight week period and recruitment rate of 12.5% (Table 4). Recruitment was initially
46
47 473 slow with six participants recruited in the first four weeks and recruitment then peaking in weeks 5 (9
48
49 474 recruited) and 8 (5 recruited) (Table 4). Researcher time was adequate to cover the necessary
50
51 475 research tasks over the course of the study.
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476 Baseline characteristics

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3 477 Participants were on average 44 years old, with the majority holding a diagnosis of recurrent
4
5 478 depressive disorder (ICD10 F33.0, 12/30 participants). Mean duration of diagnosis was 10.7 years
6
7
8 479 (range, 1-40 years). Few (3/30) had previously attended music therapy. Groups differed significantly
9
10 480 at baseline regarding gender (65% of the treatment arm were female compared to 30% in the wait-
11
12 481 list arm), self-efficacy, BSI scores and life skills of self-care and communication. The treatment arm
13
14 482 also had a greater proportion of participants with English as a second language. Depression symptom
15
16 483 severity had high variance, with participants scoring a large range of the MADRS (0-48), and BDI-II (1-
17
18 484 48). Two wait-list participants met the criteria for remission at baseline (<9) on the MADRS, while
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21
22 485 seven met criteria for mild or moderate depression on the BDI-II (3 in treatment, 4 in wait-list).

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24
25 486 <Insert Figure 1 here>

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27
28 487 <Insert Table 3 here>

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30
31 488 <Insert Table 4 here>

32
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34 489 Retention

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36
37 490 Ten participants withdrew from the study between allocation and post-intervention with 60%
38
39 491 retention (n=18) at 6-month follow-up. On allocation, one wait-list participant withdrew due to no
40
41 492 longer being able to take part. The remaining nine withdrawals were in the treatment arm, of which
42
43 493 six did not attend any sessions. Those who did not attend withdrew from both study and intervention
44
45 494 due to being unable to commit to the group schedule (n=2), life events (n=2), symptom severity (n=1)
46
47 495 and loss of contact (n=1). Of those who did attend, one was withdrawn due to risk after the first
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49
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51 496 session, one felt that the study was not of benefit to depression after four sessions and one felt further
52
53 497 study participation was invalid having only attended three sessions and gained employment. At three
54
55 498 months follow-up one further treatment participant who did not attend any sessions withdrew due
56
57
58 499 to too many other commitments and one wait-list participant due to commencing employment.

1 500 Outside of withdrawals, two separate losses to follow-up occurred, once at three months and once at
2 501 six months in the treatment arm.
3

4
5 502 Blinding
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7
8 503 There were four instances of unblinding. One post-allocation, where an intervention participant called
9
10 504 the researcher to inform of the outcome; twice when arranging one week post-intervention
11
12 505 assessments with intervention participants and one wait-list participant at the six-month follow-up.
13
14 506 In the three cases of scheduling assessments, all were due to participants sharing upcoming
15
16 507 intervention-based appointments. With two blinded team members, there was capacity within the
17
18 508 research team to cover these assessments enabling all assessments to be completed with blinding
19
20 509 intact.
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25 510 Clinical outcomes
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28 511 Raw and adjusted outcomes are shown in Tables 5 and 6 respectively.
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31 512 <Insert table 6 here>
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34 513 <Insert table 6 here>
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38 514 Primary outcome – MADRS
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41 515 Groups differed at baseline (Treatment: 25.85, Waitlist: 19.20) with greater severity in the treatment
42
43 516 group. Measures indicated a worsening of symptoms in both groups post-intervention (Treatment
44
45 517 31.28; Waitlist 25.51), with the treatment group then improving to better than baseline at 3 and 6
46
47 518 month follow-ups (3 month 19.82; 6 month 24.91). The wait-list group scored higher than baseline
48
49 519 scores at 3 and 6 months (3 month: 23.51; 6 month 23.31). The intra-class correlation coefficient,
50
51 520 demonstrating the level of clustering between groups was 0.088.
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56 521 <Insert Figure 2 here>
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522 After adjusting for baseline scores, a change of greater than the MCID (-5.04, reduction of 20.2% from
523 baseline score) was seen at 3 months in the treatment group but not at one week or 6 months post-
524 intervention (Figure 2). Four participants in each arm saw reductions of more than 39%, equating to
525 'much improved' on the Clinical Global Impressions scale. For the four treatment participants this was
526 3 and 6 months post-intervention. For the four wait-list participants this was across all follow-up
527 timepoints. Three participants qualified for remission (scores less than 9): One participant in the
528 treatment arm (compliant attender) qualified as complete remission (<5) and two in the wait-list arm
529 (<9). Both the wait-list participants in remission withdrew from the study at the point of offer of music
530 therapy.

531 Secondary outcomes

532 Treatment group scores were worse compared to the wait-list group on all secondary measures one
533 week post-intervention apart from BSI Somatisation (Treatment: 2.08; Waitlist 2.09) and BSI Hostility
534 (Treatment 1.74; Waitlist 1.88). In the treatment group, mean difference improvements from baseline
535 to one week post-intervention were seen in self-efficacy (+0.88), LSP communication (+1.64) and BSI
536 subscales of somatisation (-0.36), interpersonal sensitivity (-0.18), depression (-0.17), anxiety (-0.24),
537 hostility (-0.82), phobia (-0.17), paranoia (-0.21), psychosis (-0.15), global severity (-0.17), positive
538 symptom totals (-1.05) and positive symptom distress (-0.22). In the wait-list group, all scales scored
539 worse in mean differences from baseline to one week post-intervention apart from LSP subscales of
540 non-turbulence (+0.05), social communication (+0.07), communication (+0.49) and responsibility
541 (+0.05).

542 At 3 months, treatment group scores were more favourable compared to the wait-list group on all
543 measures except the BDI-II (Treatment 30.72; Waitlist 29.60), CSQ (Treatment 21.46; Waitlist, 22.86)
544 and WSAS (Treatment 27.71, Waitlist, 27.07). The treatment group showed mean difference
545 improvements compared to baseline on all measures apart from CSQ (-2.69), WSAS (+0.86) and LSP
546 social contact (-0.97). The wait-list group showed mean difference deterioration compared to baseline

1 547 on all measures apart from satisfaction (+0.66), LSP non-turbulence (+1.94), LSP communication
2 548 (+0.04) and BSI Obsessive Compulsive subscale (-0.02).
3
4

5 549 At 6 months, scores favoured the treatment group on CSQ (Treatment, 22.56; Waitlist, 20.17), MANSA
6
7 550 (Treatment, 3.67; Waitlist 3.41), BSI sub-scales of somatisation (Treatment 1.73; Waitlist 1.78),
8
9 551 interpersonal sensitivity (Treatment 2.18, Waitlist, 2.28), depression (Treatment 2.42; Waitlist 2.57),
10
11 552 psychoticism (Treatment 2.56; Waitlist, 2.74) and LSP Self-Care (Treatment 35.82; Waitlist 33.06),
12
13 553 Non-turbulence (Treatment 45.46; Waitlist 44.89), Communication (Treatment 22.30, Waitlist, 22.22)
14
15 554 and LSP Sum score (Treatment 137.60; Waitlist 133.91). Mean difference change compared to baseline
16
17 555 was favourable on all measures apart from BDI-II (+3.08), Satisfaction (-1.59), Self-esteem (-2.25),
18
19 556 WSAS (+6.89) and BSI Obsessive-Compulsive (+0.51). Wait-list mean difference scores deteriorated
20
21 557 compared to baseline on all measures apart from the LSP sum score and subscales (LSP SUM +0.01).
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27 558 A negative MCID was detected one week post-intervention for the treatment arm after adjusting for
28
29 559 baseline scores in the BDI-II (gain of 5.26). A positive BDI-II MCID was detected in three treatment
30
31 560 group and four wait-list group participants via reduction of 5+ points, while two treatment and four
32
33 561 wait-list participants had reductions of >30%. Two treatment participants and five wait-list
34
35 562 participants met criteria for 'minimal' depression.
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40 563 Acceptability of research methodology to professionals and patients (objective 5)
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43 564 End interviews with 10 participants and 7 clinical staff indicated generally good acceptability of the
44
45 565 research methodology and study procedures. Clinicians stated that the referral process had been easy.
46
47 566 Referrers were positive about the intervention being offered, particularly its intensity and
48
49 567 opportunities for socialisation and enjoyment. One suggested that it had been a reminder that more
50
51 568 was available than cognitive behavioural therapy (CBT). Patients declined participation mostly due to
52
53 569 not being interested or to the time commitment of attending groups. Clinicians valued researchers
54
55 570 being physically present in clinics to reduce delays between the study offer by the clinician and
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57 571 researcher contact. Written study information and weekly email reminders were appreciated
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1
2 572 alongside prompt responses to clinical queries. The music therapists reported challenges in not
3
4 573 assessing participants prior to groups and suggested that group allocations post-intervention should
5
6 574 take into account individual characteristics beyond capacity to attend a morning or afternoon group.
7
8 575 There were further challenges as the music therapists worked across more than one clinical borough,
9
10 576 requiring rapid familiarisation with wider clinical teams. Similarly, where participants did not clearly
11
12 577 fall under a specific care pathway this led in some cases, to the music therapists having to case hold
13
14 578 whilst awaiting allocation to the relevant team. Music therapists reported joint working with the
15
16 579 research team as supportive especially when linking up for weekly process measures which often
17
18 580 provided further evidence to back up clinical concerns.

20
21
22 581 Participants spoke positively about their experiences of participating in research even if their
23
24 582 experience in music therapy was less so. Some likened being invited to “winning the lottery”. Written
25
26 583 materials were helpful as were consistent and clear communication. While waiting for the allocation
27
28 584 caused some apprehension, participants felt well-enough informed to accept that this was something
29
30 585 they had signed up to. Participants valued the relationships that they built with researchers and the
31
32 586 continuity of seeing the same person each time along with flexibility for appointments. They cited
33
34 587 understanding, friendliness, support, encouragement to attend the next appointment and being
35
36 588 thanked for their time as important. The vouchers provided after assessments were welcomed and
37
38 589 cited as a good incentive to continue with research assessments. One participant suggested smaller
39
40 590 denominations so that there was more flexibility in what could be purchased.

46 591 Acceptability of outcome measures

48
49 592 Outcome measures were generally acceptable to participants with <1% of items missing. No items
50
51 593 were missing on the primary measure of the MADRS. Three participants struggled to answer CSQ
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53 594 questions relating to services before they attended music therapy (eg. CSQ-B – Did you get the kind
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55 595 of service you wanted?). A few participants declined to answer questions relating to sex (MANSAs item
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2 596 13, BDI-II item 21). Items 17, 18 (taking and accepting medication) and 25 (problems living with others)
3 597 of the LSP were most often rated as not applicable by researchers.
4

5 598 Some participants found the assessment questions anxiety provoking but the majority stated they
6
7 599 found them helpful and appreciated that they went into depth about current issues and provoked
8
9 600 reflection on how things were right now. The length of followup duration was also appreciated.
10
11 601 Participants who were less literate suggested that it was challenging to complete but that researchers
12
13 602 gave sufficient support in order to answer the questions. The most problematic assessment was the
14
15 603 LSP, which researchers found awkward to administer in a face to face interview. Introductory text was
16
17 604 added to explain the purpose of the questions to facilitate this. The CSRI also required updating when
18
19 605 participants noted that the benefits system had changed to those that were in the questionnaire.
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21 606 Participants particularly appreciated the process measures which they stated helped them to notice
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23 607 changes from week to week.
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29 608 Feasibility and acceptability of the intervention (objective 6)
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32 609 Compliance
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36 610 Mean attendance was 10.5 (SD 13.8) out of a possible 42 sessions (25%) with modes of 3 group
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38 611 members per session in one group and 2 group members per session in the other. Participants split
39
40 612 into compliant (N=6, mean 27.8/66% sessions), non-compliant (n=8, mean 3.5/8% sessions) and non-
41
42 613 attenders (n=6). Five out of six compliant attenders had lower MADRS scores than noncompliant,
43
44 614 although one compliant attender scored the maximum (range 18-48) (Figure 6).
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48 615 Reasons for non-attendance linked directly to study withdrawal. Four participants with low baseline
49
50 616 MADRS scores (<15) withdrew early on. One wait-list participant who was recruited from a CMHT
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52 617 scored 0 on the MADRS and withdrew prior to the one week post-intervention followup. Two were
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54 618 participants recruited from Talking Therapies who both withdrew due to commencing employment
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2 619 (one having attended 3 sessions). One participant recruited from the CMHT withdrew due to childcare
3 620 issues having attended one session.

4
5 621 Two out of the four participants recruited from GP practices did not attend despite scores of >30 on
6
7 622 the MADRS, one due to housing and carer issues and one due to loss of contact. The remaining four
8
9 623 non-attending participants had baseline MADRS scores ranging from 20-30 and did not attend due to
10
11 624 venue accessibility, worsening of symptoms, being unable to commit to the group and life events.

12
13 625 Of the eight non-compliant attenders, one was withdrawn to risk, two requested to withdraw from
14
15 626 the group due to group conflict and one left due to commencing employment. The remaining four
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17 627 attended over the course of therapy but faced significant challenges due to refugee status, carer
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19 628 responsibilities, homelessness and family illness.

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23 629 <Insert Figure 6 here>

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28 630 Based on low attendance figures, we opened up places to non-study participants for the wait-list
29
30 631 group. Two additional patients were offered places left by the two study withdrawals but did not
31
32 632 complete any study assessments or measures. One attended regularly and one did not attend due to
33
34 633 worsening of symptoms prior to the group starting. Of the wait-list study participants, attendance was
35
36 634 higher (mean 19.4/46%, SD 15.8) with mode of 5 participants per session. Five participants were
37
38 635 compliant (mean 30.8/73% sessions). One ceased attendance after a single session and lost contact
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40 636 with the research team, one after 6 sessions and one did not attend.

41 42 43 44 45 637 Adherence

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49 638 Mean manual adherence was 44.45% (SD 25.94) with moderate reliability when coded by an
50
51 639 independent rater. The music therapists used all components of the manual over the course of the
52
53 640 groups but with different sections being used at particular times in the therapy process (for example,
54
55 641 greater focus on introductory activities in early sessions, recording happening later on in the therapy

642 process). In the two treatment groups, seven song recordings were made. One instrumental recording
643 and a number of improvisations were made in the wait-list group.

644 The music therapists suggested that further instruction on how to complete adherence forms would
645 have built their confidence alongside a different design of the forms that allowed for a less linear
646 approach to the group process.

647 Process measures

648 Due to low attendance, process measures of mood and relationship satisfaction were available for
649 only ten participants (morning group: 6/10, afternoon group: 4/10) and only six for depression (BDI-
650 II: morning group 3/10, afternoon group 3/10). Plots of pre and post mood scores (Figure 3) suggested
651 an increase in positive energy, relaxation and reduction in tiredness and negative activation in the
652 morning group alongside improvements in relationship satisfaction (Figure 4). The afternoon group
653 demonstrated a different picture whereby earlier sessions reported an increase in negative activation
654 and lower relationship satisfaction scores in the first four weeks and less marked mood differences
655 pre and post session. For the BDI-II (Figure 5), depression scores reduced in both groups between
656 weeks 3 and 6, but then increased again between weeks 6 and 9. There was a reduction in depression
657 in week 12 in the afternoon group.

658 <Insert Figure 3 here>

659 <Insert Figure 4 here>

660 <Insert Figure 5 here>

661 Experiences of the intervention

662 Ten participants took part in qualitative interviews. In terms of group experiences, three
663 superordinate themes were identified: The group as a happy and safe place; Music stimulates new
664 feelings and songwriting aids expression into words; Uncertainty, unmet needs and the ending were
665 challenging. Further detail on these experiences of the therapy can be found in Windle et al. [85].

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666 Participants reported an average of 5 changes (range 1-9) whilst referring clinicians reported observing
667 an average of three changes in their patients. The majority of these changes were positive, the most
668 common being linked to musical engagement, changes in mood and confidence. Three participants
669 reported increased engagement in other activities whilst three reported negative changes in terms of
670 nervousness, feeling worse at the end of therapy and becoming more housebound. Three of the
671 waitlist group participants reported changes they had hoped for, but did not happen, namely: a wish
672 to change memory of trauma, to change how they thought and a wish to have been more involved in
673 the group. Participants tended to be surprised by the changes that they had noticed (65% of changes
674 were rated as 4 or 5 on the Client Change Interview expectancy-surprised scale) and believed them to
675 be unlikely to have happened without therapy (58% of changes rated as 1 or 2 on the likelihood scale).
676 All participants rated their changes as moderately to extremely important (3-5 on the importance
677 scale).

678 Accessibility of the therapy location, session frequency and managing the group ending were
679 described as challenging by participants. Participants suggested longer sessions (eg. 2 hours) but twice
680 per week would be preferable to three times per week.

681 The music therapists reported challenges in the make-up of each therapy group alongside high levels
682 of drop-out and the impact on group members. Further attention to the make-up of the group was
683 suggested post-randomisation to ensure a good mix and balance of participants.

684 The music therapists spoke positively about the potential of group songwriting for this client group,
685 especially techniques of song sharing and combining check-ins and improvisation as a basis for
686 songwriting. They reported some challenges in group songwriting that were beyond their usual scope
687 of practice. Deciding how far to intervene in the songwriting process was described as challenging in
688 the beginning but they observed greater sophistication in the groups' ability to create over time.
689 Technology, whilst opening up new musical and recording possibilities was a challenge and they
690 suggested that the manual should include more on editing and recording processes.

691 Potential harms and unintended effects

692 A total of six adverse events (four in the treatment arm, two in the control) and one serious adverse
693 event (treatment arm) were reported during the study (Table 7) in seven different participants. All but
694 one (fainting during a research assessment) were expected events.

695 <Insert Table 7 here>

696 The most frequent adverse event was increased suicide risk, identified during the research
697 assessments. One participant disclosed a risk to self/others in a follow-up assessment which appeared
698 unrelated directly to the intervention but could possibly have been related to the recent ending of the
699 group. Within the treatment arm, events that occurred during the treatment phase included one
700 verbal threat and one increased suicide risk, identified during completion of process measures. The
701 verbal threat was assessed as probably unrelated given this participant's risk history although it is not
702 possible to say for certain if events in the group were a contributing factor. Two instances of
703 homelessness were also reported which, whilst not meeting the definition of an adverse event, were
704 reported as safeguarding alerts following local Trust policies.

705 Hospitalisation of one treatment arm participant happened during the follow-up assessment period
706 and was reported as a serious adverse event. This participant did not attend any group sessions and
707 withdrew without completing further assessments.

708 Health service use (objective 7)

709 Health service contacts reduced in both groups with a greater reduction in the treatment arm. There
710 were no further hospital admissions for mental health problems in either arm post-baseline. Third
711 sector contacts for self-help and leisure activities increased from baseline in the treatment arm one
712 week post-intervention and six months followup but were reduced at three months followup.

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3 715 Discussion

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5 716 This feasibility trial piloted a group songwriting music therapy intervention for patients with long-term
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7 717 depression and assessed the feasibility and acceptability of both the intervention and of conducting a
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9 718 larger randomised controlled trial. Descriptive information on health service use was collected to
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11 719 inform a future health economic evaluation.

12
13 720 a) Feasibility and acceptability of research methodology

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16 721 The overall research methodology was feasible and acceptable. Recruitment was most successful in
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18 722 secondary care community mental health teams and via self-referrals from patient and public groups.

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21 723 Success may be due to the research team's familiarity recruiting in such services or potentially due to
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23 724 a higher threshold of symptom severity held by these services. Our approaches through GP practices

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25 725 were by letter only and it remains to be seen if recruitment could have been more successful if
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27 726 researchers were available during clinic time to speak to those who express interest to their GP.

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30 727 Similarly, there was limited success in recruiting from Talking Therapy services, possibly due to lower
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32 728 symptom thresholds and recent receipt of talking therapy. Instances of unblinding were due to

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35 729 participants contacting researchers post-randomisation. Provision of a different contact telephone
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37 730 number post-randomisation might help to manage communications and maintain blinding.

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40 731 In terms of clinical outcomes, there were differences between observer and self-reported measures
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42 732 of depression. While participants did not report large changes between assessments, both blinded

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45 733 researchers and clinicians who were interviewed, reported wider observed changes. This may be due
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47 734 to the chronicity of symptoms experienced by participants making it challenging to notice change (for

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50 735 example, the BDI-II asks for changes in the last two weeks) [87]. We would therefore propose the
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52 736 MADRS as a suitable measure for the primary outcome of a future trial alongside secondary measures

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55 737 of psychological distress, quality of life, and life skills.
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1 738 Outcomes suggest a promising effect on the reduction of depression and improved social adjustment.
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3 739 However, these improvements were not seen until 3 months post-intervention, suggesting this as the
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5 740 point at which greatest improvement might be seen. Eight treatment participants and four waitlist
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7 741 participants scored worse for their depression symptoms at post-intervention. There are two possible
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9 742 explanations. One is that for treatment participants, the ending of an intense social experience was
10
11 743 challenging and therefore measures picked up low mood for treatment participants at this endpoint.
12
13 744 Further preparation, signposting and support of participants for their 'next steps' might help to
14
15 745 ameliorate this. Alternatively, the worsening of symptoms might be attributed to the time of year the
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17 746 measures were taken as this occurred at the post-intervention followup which took place towards the
18
19 747 end of January [88-9]. Finally, symptom improvements at the post-intervention follow-up in three
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21 748 wait-list arm participants may also capture their expectancy as they awaited to start their own groups
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25 749 [90], or they might capture spontaneous improvement.

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29 750 b) Feasibility and acceptability of intervention
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32 751 While overall elements of the intervention appeared feasible, a number of areas require modification
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34 752 prior to any further testing. Attendance was poor in treatment groups, but slightly better for the wait-
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36 753 list group. A number of factors may help to explain this: Non-attending participants tended to either
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38
39 754 have a) low symptom severity scores (<15 on the MADRS), b) were recruited from Talking Therapies
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41 755 and commenced employment or c) felt there was too much going on to be able to commit to
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43 756 attendance. Childcare, housing and multiple appointment demands were the main reasons cited for
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45 757 being unable to commit. There was also a difference between morning and afternoon groups.
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48 758 Participants were given the option to choose which time they would prefer and noticeably, those with
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51 759 more severe depression scores, chose the later time in the afternoon.

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54 760 The group frequency of 3 times per week was not feasible for this client group, hindered also for many
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56 761 by the group location. Participants suggested that twice per week would be more manageable in end
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59 762 interviews. Challenges in attendance are known for this patient population [91] and a number of
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1 763 participants faced significant issues with complex life situations including homelessness, care
2 764 responsibilities and safeguarding. Modifying the session duration and frequency might also mitigate
3
4 765 the challenges faced at the end of treatment by participants and potentially improve outcomes at
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6
7 766 post-intervention. While the intervention included signposting of participants to wider community
8
9 767 arts and social opportunities at the end of treatment, few participants attended these final sessions.
10
11 768 It may therefore be important to arrange individual follow-up meetings post-intervention to review
12
13 769 therapy progress and explore next steps.
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17 770 Process measures identified important elements of the group culture that may impact upon
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19 771 outcomes. The relationship satisfaction scale in particular gave a good indication of group cohesion
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21 772 and moments of conflict within the group. It may be that greater time was required in one group for
22
23 773 the music therapists to foster trust and build a therapeutic relationship [9] prior to commencing the
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25 774 task of writing songs. It is known that early group cohesion is a predictor of later outcomes [92-3],
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27 775 thus these measures will be useful in explaining outcomes.
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32 776 The music therapists commented on the lack of control regarding group composition, resulting in
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34 777 groups with large differences in levels of musicianship and also groups where participants were
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36 778 already familiar with each other through other services. Neither of these variables were considered in
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38 779 the trial, yet both critical mass and homogeneity of musical preferences are important factors in
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40 780 therapeutic group songwriting [94-5]. In a larger randomised controlled trial, it would be challenging
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42 781 to curate group composition post-randomisation as this would rely on sufficient recruitment up-front
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44 782 and may result in long delays between consent and commencement of the intervention. This poses a
45
46 783 risk of attrition and potentially long waits for those who have enrolled onto the study as well as
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48 784 resource challenges in delivering a larger number of groups all together, rather than a more staggered
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50 785 approach [96].
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56 786 This study encountered issues in the music therapists' use of recording software as part of the
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58 787 intervention. Modifications to the intervention include more support for music therapists on editing
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1 788 and recording songs within sessions and further skills training in the technology. Participants
2 789 suggested longer sessions of up to 2 hours would be beneficial to allow for these processes. The
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4 790 adherence form also requires re-design to capture adherence to core group principles without relying
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6
7 791 upon a linear group process.
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10 792 c) Assessment of service use
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13 793 This was relatively simple to ascertain from participants although further patient and public
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15 794 involvement will be important to ensure benefits and related health economic questions are relevant
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17
18 795 and up to date.
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21 796 Consideration of intervention attendance and study withdrawals
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24 797 This study had a high number of withdrawals (N=12, 40%), most having occurred by the point of one
25
26 798 week post-intervention. It was notable that all bar one of the non-attending participants in the
27
28 799 treatment arm (N=5) chose to withdraw from the study despite encouragement to continue with
30
31 800 assessments. For these participants, elements of housing, caring and life made the thought of further
32
33 801 participation too difficult. For the one participant who did not withdraw, contact was lost and the
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35
36 802 research team were unable to complete any of the follow-up assessments with this person. All other
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38 803 withdrawals were with participants who attended fewer than ten sessions. Further examination of the
39
40 804 factors preventing group attendance is therefore important prior to conducting a future trial. Group
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43 805 attendance is known to be a challenge for this patient group [90] and strategies to address this include
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45 806 ensuring full information about the intervention, offering assessment or trial sessions and curating the
46
47 807 location and time to be as accessible as possible. Further qualitative exploration with participants for
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49
50 808 example, regarding barriers such as housing, appointments and childcare, may help to identify exactly
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52 809 how and when group music therapy may be appropriate and accessible. Further stratification of
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54 810 patient characteristics may be useful in a larger trial [97]. For example, stricter eligibility criteria on
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57 811 depression severity (eg. a cut-off score of 20 on the MADRS) may help to avoid recruiting those with
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59 812 minimal depression scores who attend fewer sessions and it may also help to identify those who will
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1 813 struggle to attend due to a greater severity of symptoms and associated life factors. Recruitment may
2 814 be most successful from secondary care mental health services and this may also aid retention.
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4 815 Similarly, it will be important to balance randomisation on core characteristics of age, gender, duration
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6
7 816 of depression and symptom severity.
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10 817 Limitations

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13 818 The study is limited by necessarily small numbers, hence all outcomes are descriptive only and may
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15 819 not be representative of any true effect. The loss of follow-up data from those participants who
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18 820 withdrew and may not have benefitted from the intervention may similarly have impacted the
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20 821 outcomes reported. However, three out of four participants who withdrew from the intervention due
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22 822 to negative experiences or feeling there was not benefit still took part in assessments and were
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25 823 included in the outcome data. Recruitment was from one NHS site in East London and therefore
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27 824 findings may be limited in their generalisability to other settings.
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30 825 Conclusion

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33 826 Based on the study feasibility criteria, a randomised controlled trial of songwriting in group music
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35 827 therapy is feasible and acceptable but further developments and modifications – especially to the
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38 828 intervention and also, the trial design are required.
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41 829 In terms of study design, recruitment should focus on community mental health teams, and link to
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43 830 patient and public forums. A recruitment rate of 4 patients per week can be expected, but time should
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45
46 831 be factored in to allow a slower recruitment rate at the start. Inclusion criteria should include
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48 832 screening for depression severity prior to informed consent. Randomisation should stratify for age,
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51 833 gender and duration of depression and include an active control to minimise any expectancy effect of
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53 834 treatment. Outcomes immediately post-intervention may be influenced by the treatment ending with
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55 835 benefits potentially detected at 3 months.
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1 836 Regarding the intervention, further piloting is required to refine the intervention and to determine
2 837 the primary end-point. Further intervention development is required to promote greater attendance
3
4 838 and group cohesion. Introductory meetings, group location and transportation should be considered
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6
7 839 carefully. Groups should be less frequent with a longer course (eg. 2 per week over 6 months) and
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9 840 require a critical mass of at least 4 members. More time is required to prepare for ending and after-
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11 841 care procedures.

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15 842 Abbreviations

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18 843 BDI-II: Beck Depression Inventory II

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21 844 BSI: Brief Symptom Inventory

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24 845 BSI ANX: BSI Anxiety subscale

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27 846 BSI DEP: BSI Depression subscale

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30 847 BSI GSI: BSI Global Severity Index

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33 848 BSI HOS: BSI Hostility subscale

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36 849 BSI IIS: BSI Interpersonal Sensitivity subscale

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39 850 BSI OC: BSI Obsessive-Compulsive subscale

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42 851 BSI PAR: BSI Paranoia subscale

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45 852 BSI PHOB: BSI Phobia subscale

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48 853 BSI PSDI: BSI Positive Symptom Distress Index

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51 854 BSI PST: BSI Positive Symptom Total

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54 855 BSI PSY: BSI Psychoticism subscale

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57 856 BSI SOM: BSI Somatisation subscale

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3 857 CI: Confidence interval
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6 858 CBASP: Cognitive behavioural analysis system of psychotherapy
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9 859 CBT: Cognitive behavioural therapy
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12 860 CD: compact disc
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15 861 CMHT: Community Mental Health Team
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18 862 CONSORT: Consolidated Standards of Reporting Trials
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21 863 CSQ: Client satisfaction questionnaire
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24 864 CSRI: Client services receipt inventory
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27 865 DMS: Dispositional Mood Scale
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30 866 EDGAR-II: Experimental Design Generator and Randomiser
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33 867 GP: General Practice
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36 868 GPSES: General Perceived Self-efficacy Scale
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39 869 HCPC: Health and Care Professions Council
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42 870 IAPT: Improving Access to Psychological Therapies
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45 871 ICD10: International Classification of Diseases and Related Health Problems (version 10)
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48 872 IPT: Interpersonal Psychotherapy
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51 873 LSP: Life Skills Profile
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54 874 LSP CAR: LSP Self-care subscale
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57 875 LSP COM: LSP Communication subscale
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60 876 LSP NON: LSP Non-turbulence subscale
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3 877 LSP RESP: LSP Responsibility subscale
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6 878 LSP SOC: LSP Social Contact subscale
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9 879 LSP SUM: LSP Sum score
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12 880 MANSAS: Manchester Short Quality of Life scale
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15 881 MADRS: Montgomery-Åsberg Depression Rating Scale
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18 882 MCID: Minimal clinically important difference
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21 883 NHS: National Health Service
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24 884 RSES: Rosenberg self-esteem scale
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27 885 RSS: Relationship Satisfaction Scale
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30 886 SD: Standard deviation
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33 887 UK: United Kingdom
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36 888 WSAS: Work and social adjustment scale
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39 889 Declarations
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42 890 Ethics approval and consent to participate
43
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46
47 893 study participation was voluntary and written informed consent was sought prior to study
48
49
50 894 participation.
51
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53 895 Consent for publication
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56 896 Not applicable
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59 897 Availability of data and materials
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1 898 The datasets used and analysed for this study are available from the corresponding author on
2 899 reasonable request.
3

4
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7
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19 905 those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.
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27 908 Authors' contributions
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29
30 909 CC conceived the study, participated in its design and coordination, analysed and interpreted the data
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32 910 manuscript. MD recruited participants, supported data collection and data entry. CB DW and JF were
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14 1201 Figure 2. Estimated marginal means of MADRS and BDI-II outcome measures adjusting for baseline
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19 1203 Figure 3. 4-Dimensional Mood and Subscales pre- and post-session, plotted by week and group.
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25 1205 Figure 5. Depression scores on the BDI-II for whole sample and by group in weeks 3, 6, 9 and 12.
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28 1206 Figure 6: Scatter plot of baseline MADRS score and number of music therapy sessions attended by
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51 1214 diagram used in this study.
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1217 Table 1. TIDieR [47] summary of the Synchrony group music therapy with songwriting intervention

TIDieR Item	Description
1 Brief name	Synchrony group music therapy with songwriting for chronic depression
2 Why	<p>Chronic depression is associated with challenges with low mood, motivation and social isolation. Group formats may promote social integration, interaction, provide emotional and social support and offer potential cost-effectiveness [3, 29].</p> <p>Music therapy has promising evidence in treating depression [31] and offers a different therapeutic encounter. The intervention may be appealing and motivating encouraging attendance and engagement. Music has an immediate (often positive) impact upon mood [34] which may reduce symptom distress and within groups (especially singing), can promote social bonding [35]. Musical improvisation may support initial nonverbal communication of feeling states and aid patients in learning to name these [41]. Group songwriting may further aid verbal expression of internal experiences and is associated with improved quality of life [33]. Patient and carer groups value the accessibility of singing and importance of an 'end product' in promoting self-esteem, self-efficacy and achievement in recovery.</p> <p>By offering a regular intensive group format, patients will have opportunities to make music together thus providing opportunities to build trust and bond with others, improve mood and build relationships. We hypothesise this will lead to short-term reduction in psychological distress and improved social functioning. The above will contribute to improved self-esteem and self-efficacy and taken as a whole, a reduction in depression symptoms. Secondary impacts of reduced depression will be improved satisfaction with services, reduced impact of depression upon work and life and improved quality of life.</p>
3 What: materials	<ul style="list-style-type: none"> • Range of large and hand held percussion instruments eg. large: Djembe drum, bongos, conga, snare, tom toms / small: cabassa, castanets, cowbell, triangle, various shakers, chimes • Tuned instruments: guitar, electric keyboard and/or acoustic piano, auto harp, xylophone, ballaphone, marimba, glockenspiel, harmonica, thumb piano, chime bars, hand bells etc. • 2-4 microphones for recording and stand • Recording equipment: zoom digital audio recover, iPad with compatible external microphone and Garageband or similar software • Amplification for ipad and electric guitar/keyboard where required • Projector to connect to Ipad for song ideas • Speakers for playback • Flipchart and blu-tack
4 What: procedures	<p>Group music therapy with songwriting, based on an adapted songwriting intervention [33] and informed by psychodynamic music therapy for depression [40] and resource-oriented music therapy [36].</p> <ol style="list-style-type: none"> 1. Pre-therapy induction session with music therapists to meet each other, set expectations, answer questions and introduce the equipment and sorts of music-making that will happen.

	<ol style="list-style-type: none"> 2. Text message reminders sent to participants to encourage group attendance 3. First session: Extended introductions, overview of 14 week schedule, group rules, introduction to songwriting. 4. General group structure and format: Instrumental/body warm up and check in. Initial sessions use reflection on a piece of music brought to the session by a group member. Music therapists encourage group discussion. Warm-up improvisation using a theme from previous discussion to prepare for song-writing. Group reflection on the experience and ideas/themes they wish to take forward into the songwriting. Group songwriting with option to rehearse and/or perform elements. End of session check in on how feeling now compared to the beginning. Reflection on the group events and decisions. 5. Sessions 2-31: Songwriting and developing group song list 6. Sessions 32-42: Group review and closure – Sessions are dedicated to reviewing the songs written, including possibility to rehearse and record or perform. Reflection on group processes and relationships.
5 Provider	Two HCPC registered NHS music therapists.
6 How	Face to face, group format, up to 10 participants per group.
7 Where	Community centre, room with space to seat up to 12 (10 participants and 2 music therapists). Some décor such as paintings, plants, natural light. Reasonable soundproofing from interior to exterior. Room to be free from interruption or loud external noise for duration of session. Wifi to enable access to the internet for song-sharing and mobile phone signal.
8 When/how much	
a) Intensity	High intensity
b) Frequency	Three sessions per week.
c) Session time	90 minutes consisting of 60 minutes session with 15 minutes pre/post for socialisation.
d) Overall duration	14 weeks
9 Tailoring	Group structure was permitted to become more flexible (in terms of improvisation and songwriting content) as sessions progressed to tailor to the evolving needs of the group. Songwriting elements are used interchangeably where appropriate to aid the songwriting process (creating lyrics, developing the song, choosing genre, developing rhythmic structure, developing verse/chorus melody, choosing mode/harmony, adding instrumental accompaniment/possibilities for improvisation, rehearsing, final song performance).
10 Modifications	Participants unable to attend regularly were encouraged and supported to stay in contact with the music therapists and to return when they could. This meant some participants attended only once or twice per week, and some did not attend for an extended period in the group therapy. Songwriting was not used in the wait-list group.
11 How well: Planned fidelity strategies and assessment	Pre-designed fidelity check-list completed by music therapists every session. Observer-rated fidelity check-list completed by independent music therapist rater.
12 How well: Actual	Mean adherence of 44.45% (SD 25.94) with moderate reliability when coded by an independent rater. All manual components were used but with different sections occurring at different points in the therapy process.

1218 Table 2. Stop-go feasibility criteria

Outcome	Method	Success criteria				Timing
		Stop	Continue, modify protocol	Continue without modification but monitor closely	Continue without modifications	
Acceptability of methodology	Recruitment & retention rates as below					End of recruitment (week 8)
	Compliance	Mean attendance <10 sessions	Mean attendance <14 sessions	Mean attendance 14 sessions	Mean attendance 14+ sessions	End of int. (week 22)
	End interviews	Unfavourable views, serious concerns	Unfavourable views, suggestions for modification	Favourable views, suggestions for modification	Favourable views, no concerns	1 month post-intervention (week 26)
Feasibility of recruitment processes	Screening rates	Identify <50 potentially eligible subjects	Identify <100 potentially eligible subjects	Identify 100-128 potentially eligible subjects	Identify >128 potentially eligible subjects	End of recruitment
	Recruitment rates	Recruit <50% of sample size	N<25 in 8wks, <5% per week	N=25-30 in 8wks, <13% per week	N=30 in 8wks, 13% per week or greater	End of recruitment
	Participation rates	Participation rate <5%	Participation rate 5-15%	Participation rate 15-25%	Participation rate 25% or greater	6 months post-intervention
	Retention rates	Attrition >75%	Attrition 50-75%	Attrition 30-50%	Attrition <30%	6 months post-intervention
	End interviews	N/A	Major suggestions to improve recruitment processes	Minor suggestions to improve recruitment processes	No suggestions to improve expressed	1 month post-intervention (week 26)
Identify N eligible participants, participant rates and retention rates	N identified by HCPs	<50 identified	50-100 identified	100-128 identified	>128 potentially eligible identified	End of recruitment
	N expressing interest	<30 express interest	30-40 express interest	40-60 express interest	>60 express interest	End of recruitment
	N providing consent	<15 provide consent	15-25 provide consent	25-30 provide consent	30 provide consent	End of recruitment post-intervention, 3 and 6 months post-intervention
	N lost to follow-up	Attrition>75%	Attrition 50-75%	Attrition 30-50%	Attrition <30%	End of recruitment post-intervention, 3 and 6 months post-intervention
Researcher time and costs per participant	Researcher diary	N/A	Researcher time exceeds allocated time requiring additional study support	Researcher time and cost only just covers time required	Researcher time and cost fully covers time required	6 months post-intervention
Appropriate outcome measures	Variability of outcome Estimate of control mean and SD of change	No difference or clinically important difference favouring control detected based on confidence limits	Difference cannot be detected based on confidence limits but data suggests improvement favouring intervention	Difference can be detected based on confidence limits	Clinically important difference can be detected based on confidence limits	End of intervention
Intervention components	Therapist adherence End interviews	Adherence <50% Serious concerns expressed regarding intervention	Adherence <50% Major suggestions to adapt intervention	Adherence 50-75% Minor suggestions to adapt intervention	Adherence >75% No concerns or suggestions to adapt intervention	End of intervention

Intervention adherence	Therapist self-rated adherence Video rated adherence	Adherence <25%	Adherence 25-50%	Adherence 50-75%	Adherence >75%	End of intervention
Estimate of cost of intervention and services received	Therapist time CSRI	Cost significantly greater than usual care, no potential to modify intervention, no indication of benefits	Cost is greater than usual care – intervention may be modified, but outcomes suggest some benefits	Cost is greater than usual care but outcomes strongly suggest benefits.	Cost is equivalent to or slightly greater than usual care, outcomes strongly suggest benefits	6 months post-intervention

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13 1220 Table 3. Baseline socio-demographic and clinical characteristics

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Baseline Characteristics	Treatment Group (n=20)	Waitlist Group (n=10)	Total (n=30)
Age	42.25 (37.09, 47.41)	48.8 (42.07, 55.53)	44.43 (40.39, 48.47)
Females:Males ^a	13:7	3:7	16:14
English First language:Second language	10:10	8:2	18:12
In Employment:Unemployed	4:16	1:9	5:25
Primary Diagnosis:			
F31	5/20	1/10	6/30
F32	3/20	2/10	5/30
F33	7/20	5/10	12/30
F41	3/20	0/10	3/30
F43	2/20	2/10	4/30
Duration Diagnosis (years)	9.80 (4.37, 15.23)	12.5 (4.14, 20.86)	10.70 (6.41, 15.00)
Hospitalised in the last year	6/20	1/10	7/30
Medication			
Antidepressants	13/20	6/10	19/30
SNRI	4/20	1/10	5/30
TCA	6/20	0	6/30
NASSA	5/20	0	5/30
SSRI	4/20	5/10	9/30

Antipsychotic	14/20	3/10	17/30
Atypical	13/20	3/10	16/30
Typical	1/20	0	1/30
Hypnotics/Anxiolytics	7/20	2/10	9/30
Benzodiazapine	1/20	0	1/30
Antihistamine	5/20	1/10	6/30
Hypnotic	1/20	1/10	2/30
Mood stabilisers	2/20	1/10	3/30
No psychiatric medication	3/20	3/10	6/30
Previous receipt of music therapy	1/20	2/10	3/30
Interest in Music -ve	3.3 (2.74, 3.87)	2.85 (2.24, 3.46)	3.15 (2.74, 3.56)
Interest in Music +ve	3.35 (3.03, 3.68)	3.65 (3.13, 4.17)	3.45 (3.19, 3.71)
MADRS	25.85 (21.61, 30.09)	19.2 (10.73, 27.67)	23.63 (19.76, 27.50)
BDI II	30.92 (25.69, 36.15)	23.56 (13.35, 33.77)	28.47 (23.78, 33.15)
CSQ	24.15 (21.57, 26.73)	22.20 (17.92, 26.48)	23.5 (21.39, 25.61)
MANSA	3.64 (3.20, 4.07)	4.03 (3.44, 4.61)	3.77 (3.43, 4.10)
RSES	22.3 (20.21, 24.59)	24.2 (20.67, 27.73)	22.93 (21.20, 24.67)
GPSES ^b	22.05 (18.97, 25.13)	26.4 (23.27, 29.53)	23.5 (21.18, 25.82)
WASAS	26.85 (23.03, 30.67)	21.80 (13.22, 30.38)	25.17 (21.54, 28.79)
BSI Somatisation ^e	2.44 (2.06, 2.81)	1.15 (0.53, 1.78)	2.00 (1.63, 2.39)
BSI Obsessive-Compulsive	2.65 (2.31, 2.99)	2.19 (1.54, 2.84)	2.50 (2.19, 2.80)
BSI Interpersonal Sensitivity ^f	2.46 (2.07, 2.85)	1.28 (0.55, 2.00)	2.06 (1.68, 2.45)
BSI Depression ^g	2.67 (2.27, 3.07)	1.81 (1.03, 2.58)	2.38 (2.00, 2.76)
BSI Anxiety ^h	2.31 (1.95, 2.68)	1.44 (0.80, 2.07)	2.02 (1.68, 2.36)
BSI Hostility ⁱ	2.56 (2.06, 3.05)	1.68 (1.25, 2.12)	2.27 (1.89, 2.64)

BSI Phobia ^j	2.51 (2.18, 2.83)	1.42 (0.47, 2.36)	2.14 (1.75, 2.54)
BSI Paranoia ^k	2.52 (1.99, 3.06)	1.77 (1.21, 2.33)	2.27 (1.86, 2.67)
BSI Psychoticism	2.72 (2.26, 3.19)	2.01 (1.25, 2.77)	2.49 (2.09, 2.88)
BSI Global Severity Index ^l	2.04 (1.65, 2.44)	1.12 (0.59, 1.66)	1.74 (1.39, 2.08)
BSI Positive Symptom Total ^m	39.90 (34.86, 44.94)	29.20 (20.27, 38.13)	36.33 (31.75, 40.91)
BSI Positive Symptom Distress Index ⁿ	2.58 (2.27, 2.91)	1.85 (1.39, 2.30)	2.34 (2.06, 2.62)
LSP Self Care ^c	32.2 (30.48, 33.92)	35.2 (32.89, 37.51)	33.2 (31.80, 34.61)
LSP Non-turbulence	40.30 (36.75, 43.85)	42.70 (40.59, 44.81)	41.1 (38.69, 43.51)
LSP Social Contact	14.90 (13.27, 16.54)	15.60 (13.01, 18.20)	15.13 (13.83, 16.44)
LSP Communication ^d	20.05 (18.71, 21.39)	22.10 (21.12, 23.08)	20.73 (19.75, 21.71)
LSP Responsibility	17.35 (16.04, 18.66)	18.30 (16.72, 19.88)	17.67 (16.69, 18.64)

^a Wilcoxon-Mann-Whitney, $z=-2.096$, $p=.04$ ^bTwo-tailed t-test, unequal variances assumed, $p=.04$; ^cTwo-tailed t-test, unequal variances assumed, $p=.03$; ^{d-n}Two-tailed t-test, unequal variances assumed, ^d $p=.01$; ^e $p<.01$; ^f $p<.01$; ^g $p=.05$; ^h $p=.02$ ⁱ $p<.01$; ^j $p=.03$; ^k $p=.05$; ^l $p<.01$; ^m $p=.03$; ⁿ $p<.01$;

Baseline data: mean (95% confidence interval)

1233 Table 4. Weekly recruitment rates

Week	N recruited	Cumulative total	Weekly Percentage	Cumulative percentage
1	0	0	0%	0%
2	1	1	3%	3%
3	3	4	10%	13%
4	2	6	7%	20%
5	9	15	30%	50%
6	6	21	20%	70%
7	3	24	10%	80%
8	6	30	20%	100%

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1235 Table 5. Raw outcomes post-intervention, 3 and 6 months post-interventions

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Table 5. Raw outcomes post-intervention, 3 and 6 months post intervention.

	Post-intervention Raw Scores						3 Month Raw Scores						6 Month Raw Scores					
	Treatment group N=10			Waitlist group N=9			Treatment group N=9			Waitlist group N=9			Treatment group N=10			Waitlist group N=8		
	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI
MADRS	33.60	8.91	27.23, 39.97	23.44	13.89	12.76, 34.12	21.67	9.12	14.65, 28.68	21.44	12.08	12.16, 30.73	25.70	8.98	19.27, 32.13	22.00	10.81	12.96, 31.04
BDI-II	39.18	8.32	33.23, 45.13	25.29	11.43	16.51, 34.07	33.78	15.08	22.18, 45.37	26.28	11.89	17.14, 35.41	35.70	13.81	25.82, 45.58	26.89	14.50	14.77, 39.01
CSQ	21.80	6.11	17.43, 26.17	20.78	6.65	15.67, 25.89	22.22	8.06	16.03, 28.42	22.22	6.74	17.04, 27.40	23.60	8.68	17.39, 29.81	18.88	5.59	14.20, 23.55
MANSA	2.90	0.85	2.29, 3.51	3.95	0.97	3.21, 4.70	3.43	1.22	2.49, 4.36	4.07	1.03	3.28, 4.86	3.24	0.85	2.63, 3.85	3.86	1.47	2.63, 5.08
RSES	18.20	4.98	14.63, 21.77	23.78	4.09	20.64, 26.92	22.22	7.61	16.37, 28.07	24.67	4.72	21.04, 28.29	21.10	7.61	15.66, 26.54	25.13	5.57	20.47, 29.78
GPSES	21.50	8.13	15.69, 27.31	26.11	4.31	22.80, 29.43	24.56	7.97	18.43, 30.68	26.22	4.79	22.54, 29.90	22.30	7.20	17.15, 27.45	24.13	5.38	19.62, 28.63
CVSAS	31.10	6.08	26.75, 35.45	21.56	10.56	13.44, 29.67	30.22	11.51	21.38, 39.07	23.67	9.21	16.59, 30.74	30.60	4.72	27.22, 33.98	22.50	10.31	13.88, 31.12
BSI SOM	2.67	0.88	2.04, 3.30	1.50	0.74	0.94, 2.07	1.86	1.08	1.03, 2.69	1.46	0.70	0.92, 2.00	2.10	1.00	1.39, 2.82	1.32	0.69	0.75, 1.90
BSI OC	3.02	0.82	2.44, 3.61	2.13	0.72	1.57, 2.68	2.59	1.03	1.80, 3.39	2.01	0.84	1.37, 2.66	2.78	0.78	2.22, 3.34	2.21	0.91	1.45, 2.97
BSI IP	2.93	0.85	2.32, 3.53	1.62	1.00	0.85, 2.39	2.68	1.13	1.81, 3.54	2.25	0.81	1.63, 2.87	2.58	0.99	1.87, 3.28	1.80	0.96	1.00, 2.60
BSI DEP	2.98	0.94	2.31, 3.65	1.88	1.11	1.02, 2.73	2.84	1.17	1.94, 3.74	2.16	0.93	1.45, 2.88	2.74	1.15	1.91, 3.56	2.19	0.97	1.38, 3.00
BSI ANX	2.40	0.71	1.89, 2.91	1.57	0.97	0.83, 2.32	2.16	1.20	1.23, 3.08	1.87	0.79	1.27, 2.48	2.36	0.81	1.78, 2.94	1.71	0.71	1.12, 2.31
BSI HOS	2.12	0.93	1.45, 2.79	1.51	1.16	0.62, 2.40	2.01	1.09	1.16, 2.85	1.70	0.79	1.09, 2.31	2.25	1.04	1.50, 2.99	1.49	0.93	0.71, 2.27
BSI PHO	2.76	0.64	2.31, 3.22	1.49	1.16	0.60, 2.38	2.48	1.09	1.64, 3.32	1.55	1.08	0.72, 2.39	2.52	1.05	1.76, 3.27	1.74	0.97	0.93, 2.55
BSI PAR	2.81	0.85	2.20, 3.42	1.69	0.62	1.22, 2.17	2.78	0.90	2.09, 3.47	1.90	0.72	1.34, 2.46	2.68	0.87	2.06, 3.30	1.75	0.82	1.06, 2.44
BSI PSY	3.03	0.87	2.41, 3.65	1.89	1.25	0.93, 2.85	2.99	1.27	2.02, 3.96	1.80	1.15	0.91, 2.68	2.91	0.90	2.26, 3.55	2.36	1.09	1.45, 3.28
BSI GSI	2.41	0.79	1.85, 2.97	1.25	0.73	0.68, 1.81	2.15	0.91	1.45, 2.85	1.29	0.73	0.73, 1.85	2.28	0.87	1.66, 2.90	1.31	0.68	0.74, 1.88
BSI PST	44.40	7.46	39.07, 49.73	31.89	13.01	21.89, 41.89	40.44	15.23	28.74, 52.15	32.78	10.99	24.33, 41.22	44.20	12.79	35.05, 53.35	33.38	11.39	23.85, 42.90
BSI PSDI	2.80	0.73	2.28, 3.32	1.92	0.51	1.52, 2.31	2.61	0.71	2.06, 3.16	1.94	0.64	1.44, 2.43	2.62	0.67	2.14, 3.09	1.95	0.70	1.36, 2.54
LSP CAR	30.30	2.95	28.19, 32.41	34.44	3.50	31.75, 37.14	34.44	2.83	32.27, 36.62	34.33	3.43	31.70, 36.97	35.30	2.11	33.79, 36.81	33.75	3.69	30.66, 36.84
LSP NON	38.80	5.33	34.99, 42.61	43.00	2.18	41.32, 44.68	43.67	3.81	40.74, 46.59	44.89	2.62	42.88, 46.90	45.40	2.27	43.78, 47.02	45.13	3.27	42.39, 47.86
LSP SOC	13.50	4.93	9.98, 17.02	15.44	4.48	12.00, 18.88	14.56	4.82	10.85, 18.26	14.56	5.17	10.58, 18.53	15.90	4.12	12.95, 18.85	15.13	4.42	11.43, 18.82

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LSP COM	21.40	2.01	19.96, 22.84	22.78	1.20	21.85, 23.70	22.22	1.92	20.74, 23.70	22.33	1.22	21.39, 23.27	22.20	0.92	21.54, 22.86	22.38	1.60	21.04, 23.71
LSP RES	16.40	1.58	15.27, 17.53	18.44	1.01	17.67, 19.22	18.44	1.59	17.22, 19.67	17.67	1.41	16.58, 18.75	18.20	2.04	16.74, 19.66	18.50	1.20	17.50, 19.50
LSP SUM	120.4	8.28	114.5, 126.3	134.11	10.14	126.3, 141.9	133.3	9.72	125.9, 140.8	133.8	9.88	126.2, 141.4	137.0	6.43	132.4, 141.6	134.9	9.20	127.2, 142.6

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Table 6. Outcomes post-intervention, 3 and 6 months post-intervention adjusted for baseline characteristics

	Post intervention						3 months						6 months					
	Treatment group N=10			Waitlist group N=9			Treatment group N=9			Waitlist group N=9			Treatment group N=10			Waitlist group N=8		
	Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI	
MADRS	31.28	25.03	37.53	25.51	18.95	32.08	19.82	13.36	26.28	23.51	17.04	29.98	24.91	18.79	31.03	23.31	16.46	30.16
BDI-II	35.87	30.03	41.71	28.61	22.46	34.75	30.72	22.97	38.48	29.60	21.83	37.36	34.08	27.30	40.85	29.03	21.45	36.62
CSQ	21.36	17.48	25.24	21.41	17.31	25.51	21.46	16.84	26.08	22.86	18.24	27.47	22.56	17.69	27.43	20.17	14.71	25.62
MANSA	3.35	2.87	3.83	3.43	2.92	3.94	3.89	3.59	4.20	3.55	3.24	3.85	3.67	3.19	4.16	3.41	2.87	3.96
RSES	19.45	17.53	21.37	22.31	20.28	24.34	23.73	21.17	26.28	23.20	20.65	25.75	21.95	19.45	24.46	24.10	21.30	26.90
GPSES	22.93	20.14	25.72	25.01	22.07	27.95	25.20	22.44	27.96	25.12	22.35	27.88	22.94	20.52	25.37	23.29	20.58	26.01
WSAS	27.82	24.20	31.44	24.96	21.14	28.77	27.71	21.59	33.83	27.07	20.92	33.22	28.69	24.94	32.45	24.16	19.98	28.34
BSI SOM	2.08	1.65	2.51	2.09	1.64	2.54	1.36	0.81	1.90	2.04	1.49	2.60	1.73	1.29	2.17	1.78	1.29	2.28
BSI OC	2.84	2.36	3.32	2.28	1.78	2.78	2.47	1.91	3.04	2.17	1.60	2.74	2.70	2.20	3.21	2.33	1.76	2.89
BSI IIS	2.28	1.87	2.68	2.26	1.84	2.68	2.15	1.44	2.85	2.89	2.18	3.59	2.18	1.89	2.46	2.28	1.96	2.60
BSI DEP	2.50	2.03	2.96	2.37	1.88	2.87	2.40	1.84	2.97	2.66	2.09	3.23	2.42	1.97	2.86	2.57	2.07	3.06
BSI ANX	2.07	1.66	2.47	1.84	1.41	2.26	1.96	1.35	2.56	2.14	1.53	2.75	2.24	1.89	2.59	1.92	1.53	2.31
BSI HOS	1.74	1.24	2.24	1.88	1.35	2.40	1.71	1.29	2.14	2.07	1.64	2.50	2.00	1.44	2.56	1.77	1.15	2.40
BSI PHOB	2.34	2.01	2.67	1.89	1.55	2.24	2.14	1.67	2.60	1.96	1.49	2.43	2.25	1.84	2.66	2.09	1.63	2.55
BSI PAR	2.31	1.90	2.73	2.16	1.73	2.60	2.36	2.04	2.68	2.37	2.05	2.69	2.39	2.11	2.67	2.15	1.83	2.47
BSI PSY	2.57	2.13	3.01	2.39	1.92	2.85	2.56	2.02	3.11	2.29	1.75	2.84	2.56	2.18	2.94	2.74	2.32	3.16
BSI GSI	1.87	1.57	2.17	1.77	1.45	2.08	1.71	1.36	2.05	1.82	1.47	2.16	1.95	1.69	2.21	1.73	1.44	2.02
BSI PST	38.85	34.16	43.53	38.21	33.25	43.17	35.37	30.12	40.62	39.10	33.80	44.40	39.73	35.06	44.39	37.40	32.21	42.59
BSI PSDI	2.37	2.12	2.62	2.31	2.05	2.57	2.27	2.00	2.54	2.33	2.06	2.60	2.39	2.17	2.60	2.27	2.03	2.51
LSP CAR	31.11	29.15	33.06	33.67	31.62	35.73	35.12	33.68	36.57	33.56	32.11	35.01	35.82	34.05	37.60	33.06	31.08	35.05

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LSP NON	39.18	36.86	41.50	42.75	40.31	45.19	43.89	42.12	45.66	44.64	42.87	46.42	45.46	43.26	47.66	44.89	42.43	47.35
LSP SOC	13.45	11.56	15.33	15.67	13.68	17.66	13.93	11.37	16.49	14.78	12.22	17.34	15.47	13.34	17.59	15.93	13.56	18.31
LSP COM	21.69	20.53	22.85	22.59	21.37	23.81	22.31	21.41	23.22	22.14	21.24	23.05	22.30	21.55	23.04	22.22	21.39	23.06
LSP RESP	16.52	15.69	17.34	18.35	17.49	19.22	18.50	17.56	19.45	17.57	16.63	18.52	18.26	17.01	19.52	18.42	17.02	19.83
LSP SUM	122.34	117.45	127.23	132.68	127.55	137.81	134.23	129.26	139.20	132.34	127.36	137.33	137.60	132.12	143.08	133.91	127.78	140.05

Table 7. Adverse events and classification by treatment arm

Event	Classification	During treatment	During follow-up assessments	Treatment N=20	Control N=10	Expected?	Related?
Verbal threat	Adverse Event	1	0	1	0	Expected	Probably unrelated
Increased suicide risk	Adverse Event	1*	2	2	1	Expected	Unrelated
Disclosure of risk to self/others	Adverse Event	0	1	1	0	Expected	Probably unrelated
Hospitalisation	Serious Adverse Event	0	1	1**	0	Expected	Unrelated
Faint during research assessment	Adverse Event	0	1	0	1	Unexpected	Unrelated
Homelessness	Safeguarding alert	2	0	2	0	Unexpected	Unrelated
Total Number of events		4	5	7	2		

*Risk identified during research assessment after the therapy group

**Participant did not attend any group sessions

[Click here to view linked References](#)

1 Group music therapy with songwriting for adult patients with long-term depression (SYNCHRONY
2 study): A feasibility and acceptability study of the intervention and parallel randomised controlled
3 trial design with wait-list control and nested process evaluation

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23 Abstract:

24 Background: Despite effective treatments, one fifth of patients develop chronic depression. Music
25 therapy may offer a different approach. This study aimed to assess feasibility and acceptability of a
26 music therapy intervention and trial methodology.

27 Methods: A parallel two-arm randomised controlled trial with wait-list control, mixed
28 feasibility/acceptability measures and nested process evaluation. Adults with long-term depression
29 (symptom duration >1 year) were recruited from community mental health services and computer
30 randomised to 42 sessions of group music therapy with songwriting three times per week or wait-list
31 control. Depression, social functioning, distress, quality of life, satisfaction and service use were
32 assessed by blinded researchers at enrolment, one week, three and six months post-therapy.
33 Outcomes were analysed descriptively, controlling for baseline covariates. Recruitment (number
34 eligible, participation and retention rates) and intervention (fidelity, adherence) feasibility were
35 assessed using predefined stop-go criteria. Attendance, adverse events, mood, relationship
36 satisfaction and semi-structured interviews were analysed in a nested process evaluation.

37 Results: Recruitment processes were feasible with 421 eligible, 12.7% participation and 60% (18/30)
38 retention. Thirty participants were randomised to intervention (N=20) and control (N=10). Session
39 attendance was low (mean 10.5) with four withdrawals. Music therapist adherence was good but
40 changes to session frequency were suggested. Outcomes were available for 10/20 treatment and 9/10
41 wait-list participants. Depression increased in both arms post-therapy. Treatment depression scores
42 fell below baseline 3 and 6 months post-therapy indicating improvement. Wait-list depression scores
43 increased from baseline 3 and 6 months post-therapy. At three months, the treatment arm improved
44 from baseline on all measures except satisfaction and functioning. At six months, quality of life,
45 distress and functioning improved with reduction in health service contacts. High-attending
46 participants improved more than low-attending. Seven adverse events (one serious) were reported.

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47 ~~High attending participants improved more than low attending. Seven adverse events (one serious)~~
48 ~~were reported.~~

49 Limitations: As this was a feasibility study, clinical outcomes should be interpreted cautiously.

50 Conclusion: A randomised controlled trial of group music therapy using songwriting is feasible with
51 inclusion criteria and session frequency modifications, but further intervention development is
52 required.

53 Trial Registration: ISRCTN18164037 on 26.09.2016.

54 Funding: National Institute for Health Research, Research for Patient Benefit (PB-PG1014-35053)

55 Key words: Chronic depression; Long-term depression; Group Music Therapy; Songwriting;
56 Randomised controlled trial; Feasibility

57 Key messages regarding feasibility

- 58 • What uncertainties existed regarding the feasibility?

59 Music therapy is a promising intervention for depression but has not been tested in a group
60 songwriting format for long-term depression. We were also uncertain about the numbers that would
61 meet our definition of long-term depression and how best to identify and recruit them to our study.

- 62 • What are the key feasibility findings?

63 The study methods were feasible and acceptable to participants and we were able to recruit sufficient
64 numbers within the timeframe required. Group attendance was low, with a high proportion not
65 attending a single session, and initial high attrition. Inclusion criteria may require a more stringent
66 assessment of depression severity and this may aid identification of participants more likely to attend
67 the intervention. Outcomes suggested a worsening of symptoms post-intervention in both arms
68 before improvements three months later. The intervention requires further modification in terms of

69 frequency, location, music therapist technological support and support for group members once the
70 groups come to an end.

- 71 • What are the implications of the feasibility findings for the design of the main study?

72 Recruitment is most successful from secondary mental health services, with options for patient self-
73 referrals. Further development of the intervention and piloting to determine the primary endpoint
74 are required before a larger trial is implemented.

75 Background

76 The global burden of depression is well-recognised: Despite many effective treatments, around one in
77 five diagnosed with an acute depressive disorder develop chronic depression [1]. The severity and
78 course of symptoms vary from 'milder' symptoms of dysthymia to chronic major depression [2]. For
79 this specific patient group, median durations are estimated between five to twenty years [3,4] with
80 associated increased health care costs through greater use of services and rates of hospitalisation [5-
81 7]. Known risk factors include younger age of onset, childhood adversity and abuse [8-18], family
82 history of mood disorder and problems within the social environment (such as low social integration,
83 support and negative social interaction) [3].

84 Chronic or persistent depression is defined by symptoms lasting 2 or more years. However, durations
85 of 1 year or longer are still both clinically relevant (in terms of distress) and may be indicative of a
86 chronic course [8, 19]. Around 40% of chronically depressed patients fulfil the criteria for treatment
87 resistance, which can be identified as soon as 6 months post-diagnosis (or after two trials of
88 antidepressant drugs)[20]. This suggests that symptoms enduring for one year or longer are both an
89 indicator of future chronicity and a need for further intervention. For the purposes of this study, we
90 use the term 'long-term depression' to define patients with symptoms of depression that have lasted
91 one year or longer.

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92 Treatment of long-term depression is particularly difficult: Frequent relapses can lead to pessimism
93 and demoralisation of both patient and professional [4] leading in turn, to lack of compliance or ‘giving
94 up’ on treatment. There is evidence for both pharmacotherapy [21-2] and psychotherapy [23] as
95 effective treatments. These effects appear to be maximised when used in combination [24] although
96 around 18 sessions of psychotherapy may be necessary in order to see clinical effects [25]. A later
97 review found limited evidence for their use in combination [26] but suggested psychotherapy might
98 have a continued role in promoting and maintaining treatment adherence, given patient preferences
99 are often for psychotherapy over medication and achieving wider clinical benefits (such as improved
100 coping strategies and quality of life). As a result, clinical guidelines recommend combined treatment
101 with a personalised approach [9].

102 There is good evidence for psychotherapy interventions that target interpersonal problems (such as
103 the cognitive behavioural analysis system of psychotherapy (CBASP) and interpersonal psychotherapy
104 (IPT) [27]. Similarly, long-term psychoanalytic psychotherapy has been shown to improve long-term
105 outcomes in treatment resistant depression [28]. Given the social environment is a known risk factor
106 for this population [3,29], group formats may promote social integration, interaction, provide
107 emotional and social support and offer potential cost-effectiveness.

108 Group music therapy

109 Music therapy is a complex intervention provided by music therapists that uses a range of expressive
110 and receptive musical activities, verbal reflection and the relationships developed through this to
111 improve health [30]. Within the United Kingdom (UK), music therapists are regulated by the Health
112 and Care Professions Council (HCPC) and must have completed accredited Masters level training.
113 Within the UK, practice most often uses a combination of active musical improvisation and verbal
114 reflection within sessions, which can take an individual or group format.

115 There is promising evidence for the effectiveness of music therapy in treating depression [31] and it
116 may benefit this population for several reasons. As an intervention, it may be appealing and

117 motivating given the different focus on use of the art form and thus encourage attendance and
118 engagement [32-3]. The experience of making music provides a very different therapeutic encounter;
119 music has an immediate impact (often positive) on mood [34] and within groups (especially singing),
120 can promote social bonding [35]. A positive experience within a community-based group may then
121 place the person in contact with their musical and psychological 'resources' [36], which – linking to
122 wider theories of recovery in mental illness- may provide opportunities to build inner resources of
123 coping, resilience and promote hope [37-8].

124 Through co-created musical improvisation it is possible to give sound to, experience, express and
125 transform feeling states, form relationships and communicate with others without words. These
126 experiences may promote opportunities for more positive social interactions than those experienced
127 verbally. The musical attunement facilitated by music therapists when improvising may help patients
128 to experience nonverbal social contact, closeness, emotional containment and address feelings of
129 social isolation [39]. This process is implicated in building initial therapeutic trust, which is an
130 important factor for this patient group [40]. Notably, a randomised controlled trial of individual
131 psychodynamic improvisational music therapy for depression [41] found additional benefits on
132 alexithemia, suggesting that musical improvisation assisted patients in naming internal feeling states.

133 A further music therapy trial used group songwriting for patients with severe mental illness and
134 demonstrated improved quality of life [33]. Creating bespoke songs as a group has the potential for
135 participants to begin to find ways of putting their internal experiences into words and to have this
136 supported through group discussion and music making [42].

137 Clinical benefits are associated with the number of sessions received. One meta-analysis [43]
138 suggested around 4 sessions would be required for a small effect on depressive symptoms, 10 for a
139 medium effect and 16 for a large effect. The impact of session frequency and duration is less clear.
140 Within the UK, sessions are often offered on a weekly basis. However, internationally, frequency can
141 range from 1-6 sessions per week [43].

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142 In designing the intervention for this study, we consulted with patient and carer groups, who
143 suggested that singing would be a more accessible and acceptable way of making music than
144 instrumental improvisation. They also emphasised the importance of having an 'end product' in
145 promoting self-esteem, self-efficacy and achievement in their recovery. We therefore took a group
146 songwriting protocol [33] as our starting point and through focus groups with music therapists and
147 clinical psychologists and interviews with patients with depression, incorporated principles from
148 psychodynamic improvisational music therapy [40] and resource-oriented music therapy [36, 44].

149 By offering a regular intensive group format (3 sessions per week), we hypothesised that patients
150 would have opportunities to make music together thus providing opportunities to build trust and bond
151 with others, improve mood and build relationships. We hypothesised this could lead to a range of
152 relevant outcomes such as short-term reduction in psychological distress and improved social
153 functioning. The above could also contribute to improved self-esteem and self-efficacy and taken as a
154 whole, a reduction in depression symptoms. Secondary impacts of a reduction in depression were
155 hypothesised to be improved satisfaction with services, a reduced impact of depression upon work
156 and life and improved quality of life.

157 Current evidence suggests group music therapy may offer an alternative and potentially clinically
158 beneficial treatment for long-term depression. However, the intervention has not been specified or
159 tested specifically for this population using a group and songwriting format within a UK National
160 Health Service (NHS). Whilst music therapy is commonly provided in NHS mental health care, provision
161 is often to diagnostically heterogeneous groups. Similarly, whilst songwriting is a recognised music
162 therapy technique, it is less frequently used in the UK. It was therefore important to assess whether
163 the intervention was delivered as described and its general acceptability to both patients and music
164 therapists.

165 In terms of the research design, it was important to assess our proposed methods for identifying,
166 recruiting and retaining participants. In particular, we were unsure of the numbers who might meet

167 our definition of 'long-term' depression, where they might be identified within services, nor of the
168 best ways to identify them. Running the study on a small scale enabled us to examine how feasible
169 our proposed processes were and to estimate the resources and most effective approaches required
170 [45]. We were similarly unsure which measures might be most appropriate in terms of acceptability
171 of completion, the variability of outcomes and what level of clustering might be expected within
172 groups.

173 Aims and objectives

174 This study aimed to pilot a group songwriting music therapy intervention for patients with long-term
175 depression and assess the feasibility and acceptability both of the intervention and of conducting a
176 larger randomised controlled trial. In addition, the study sought to gather descriptive information on
177 health service use in order to inform a future health economic evaluation.

178 Objectives

179 a) Feasibility and acceptability of research methodology

180 1. Assess the feasibility of recruitment processes

181 2. Identify the number of eligible participants, participation and retention rates

182 3. Assess the researcher time required

183 4. Assess the appropriateness of outcome measures, including providing data on the variability of
184 outcome, an estimate of the control group mean and the intra-cluster correlation coefficient.

185 5. Assess the acceptability of the research methodology to professionals and patients

186 b) Feasibility and acceptability of intervention

187 6. Assess the intervention in terms of testing use of components, measuring adherence and estimating
188 the likely intervention effect.

189 c) Assessment of service use for health economic evaluation

190 7. Assess the services received by participants in preparation for a health economic evaluation.

191 Methods

192 A parallel two-arm randomised controlled feasibility trial with mixed methods evaluation. Participants
193 were assessed at the point of enrolment (baseline), the week post-intervention, 3 and 6 months post-
194 intervention. Shopping vouchers of £10 were offered at baseline and for subsequent assessments for
195 treatment participants. Wait-list participants were paid £15 per follow-up to acknowledge the delay
196 to treatment. The study was given favourable ethical opinion from the Health Research Authority
197 (IRAS project ID: 198964, REC reference:16/WA/0248) and the study protocol was published with open
198 access in March 2017 [46].

199 Four amendments were made during the study. We amended the patient information sheet and
200 consent form to include the possibility of payment for travel to therapy sessions where patients did
201 not hold a 'freedom pass'; a substantial amendment was made to move the post-test assessment
202 point from one month post-intervention to immediately at the intervention end to maximise follow-
203 up rates and capture any immediate treatment effects; we clarified payment of £10 for participation
204 in qualitative interviews to ensure consistency with previous assessments; finally, prior to
205 commencing music therapy for the wait-list group, we opened up two spaces to patients outside the
206 study to ensure a critical mass of group members could be maintained.

207 Eligibility criteria

208 As this was a feasibility trial, our inclusion criteria were as broad as possible. Participants were eligible
209 if they had a confirmed diagnosis in the International Classification of Diseases and Related Health
210 Problems (version 10) (ICD10), of depression (ICD10 F31-39), including post-schizophrenic depression
211 (ICD10 F20.4) and prolonged depressive reaction (ICD10 F43.21), had received pharmacological
212 and/or psychological treatment for 12 months or longer, were aged 18 years or above and had

213 capacity to give written informed consent. We excluded any diagnosis of organic mental disorder
214 (ICD10 F00-09), bipolar affective disorder if current manic episode (ICD10 F30, F31.0, F31.2, F31.6,
215 F31.7-4), if they lacked capacity to give informed consent or were at risk of suicide necessitating
216 hospitalisation. Previous receipt of music therapy or other psychological therapies did not form part
217 of the eligibility criteria, but were recorded as part of baseline clinical characteristics.

218 Setting and participant identification

219 The study took place in East London NHS Foundation Trust. Research assistants recruited participants
220 via: a) primary care, via General Practice (GP) surgeries, b) secondary care via improving access to
221 psychological therapies (IAPT) services and community mental health care teams. GP surgeries were
222 invited to sign up to act as recruiting centres. A practice staff member then sent letters of invitation
223 to any potentially eligible patients. Within secondary care, caseloads were screened by a clinical
224 studies officer who was part of the care team and potential participants were approached by the
225 professional responsible for their care. An unexpected third means of recruitment was via patient self-
226 referral through presentations about the study to patient and carer groups across the Trust. Where
227 patients expressed interest, permission was gained to contact their healthcare professional to check
228 eligibility and then a meeting arranged to go through informed consent.

229 Participant consent

230 Recruitment lasted for 8 weeks between September and November 2016. Interested patients were
231 provided with an information sheet and then met with a member of the research team to give written
232 informed consent and complete baseline measures. To support retention, we aimed wherever
233 possible for the researcher conducting baseline assessments to continue with that participant for all
234 follow-up assessments.

235 Intervention (Group music therapy with songwriting)

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237 The Synchrony group music therapy with songwriting intervention is summarised according to the
238 Template for Intervention Description and Replication (TIDieR) checklist [47] in Table 1. A manual for
239 the Synchrony group music therapy with songwriting intervention [Additional File 1], based on Grocke
240 et al. [33] and informed by individual psychodynamic music therapy for depression [40] and resource-
241 oriented music therapy [36] was developed prior to the study taking place through focus groups with
242 music therapists, psychologists and interviews with patients with depression. The manual was
243 finalised through regular meetings with the music therapists providing the intervention and Heads of
244 Arts Therapies.

245 Adaptations to Grocke et al.'s intervention [33] included group members sharing pre-known songs in
246 the early phases of the group; group improvisation after ice-breaker activities and before working on
247 songs; and building time for the group to decide what they would like their end product to be (eg. a
248 compact disc (CD) or a group performance). Unlike Grocke et al. [33] who used a recording studio at
249 the end of therapy, recording took place during the music therapy sessions using GarageBand software
250 [48] and formed a major part of the group process.

251 Based on feedback from patient and carer groups, group music therapy took place in non-NHS
252 premises in a community centre within one London borough. The centre offered facilities for
253 additional social contact, such as a café and wider non-medical community groups. Sessions were
254 provided three times per week over 14 weeks by two HCPC-registered music therapists. Sessions
255 lasted 90 minutes and consisted of opening warm-up activities (such as passing an instrument),
256 sharing current state (which, with permission, was written onto a flip chart for later lyric writing) and
257 then moving into group improvisation. Music therapists transitioned into songwriting from this point,
258 focusing on lyric creation, musical ideas or motifs and later recording. Opportunities were offered
259 after each activity for verbal reflection. The last 15 minutes were dedicated to reviewing the session
260 either through group discussion, or by playing music together.

261 Wait-list control

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262 The wait-list control group received treatment as usual for the study duration, which involved either
263 psychopharmacological medication, psychological therapy or a combination. At the end of the final
264 follow-up assessment, a further songwriting music therapy group was offered to these participants.

265 Assessment measures

266 The purpose of a feasibility study is to determine whether or not it is possible to proceed with a given
267 intervention or research design before moving to a larger scale [49]. In order to do this, it is
268 recommended to establish pre-defined stop-go criteria [49] to aid the decision of whether or not to
269 proceed. While the criteria can vary from study to study, many take the format of a 'traffic light'
270 system to aid identification of thresholds where a criterion is feasible ('green'), not feasible ('red') or
271 potentially feasible with modifications ('amber'). Our pre-defined stop-go criteria were published in
272 the study protocol [46] and are summarised in Table 2.

273 <Insert Table 2 here>

274 a) Feasibility/acceptability of the research methodology (objectives 1-5)

275 Feasibility of recruitment processes (objective 1) and identification of the number of eligible
276 participants, participation and retention rates (objective 2) were assessed through descriptive analysis
277 of recruitment and drop-out rates and qualitative end interviews with participants and referring staff.
278 Researcher time (objective 3) was assessed through researchers keeping logs of contact, dates of visits
279 and time taken throughout the study. Outcome measure appropriateness (objective 4) was assessed
280 by examining descriptive statistics and missing data. For clinical outcomes, our proposed primary end-
281 point was in the week following the intervention end (post-intervention), with secondary endpoints 3
282 and 6 months post-intervention. Acceptability of the research methodology to participants and
283 patients (objective 5) was assessed through thematic analysis of qualitative interviews at the end of
284 intervention.

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286 b) Feasibility/acceptability of the intervention (objective 6)

287 Feasibility/acceptability of the intervention (objective 6) was assessed through a nested process
288 evaluation which aimed to understand a) how the intervention was delivered in practice (treatment
289 fidelity analysis), b) Describe processes of attendance and hypothesised process factors of self-
290 reported depression, mood and group relationships from week to week and c) understand subjective
291 experiences and attributions for change of the intervention from the perspective of patients, music
292 therapists and referring staff. To assess treatment fidelity, music therapist self-reported adherence to
293 the manual each session and video analysis of 25% of sessions by independent raters (both music
294 therapists) was collected using the same adherence proforma. To examine attendance and
295 hypothesised process factors, group attendance, self-reported depression and weekly process
296 measures of mood and group relationships were collected. For subjective experiences and change
297 attributions, end of therapy interviews were conducted with patients and music therapists using the
298 Client Change Interview [50]. This was adapted for referring staff and music therapists to reflect on
299 changes observed in participants. Qualitative interviews were conducted by unblinded members of
300 the research team and clinical studies officers supporting the study. Finally, as part of good clinical
301 practice, adverse events were monitored throughout the study and were considered in relation to
302 intervention safety and potential adverse outcomes.

303 c) Health service use (objective 7)

304 Health service use data were collected by examining medical records for any hospitalisation and using
305 the Client Services Receipt Inventory at baseline, in the week following the intervention (post-
306 intervention), 3 and 6 months post-intervention.

307 Proposed primary symptom outcomes

308 Both observer-rated and self-report measures were used to assess depression symptoms.

309 *Montgomery-Åsberg Depression Rating Scale (MADRS) [51]*

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310 The MADRS is an observer rated 10-item scale known to be sensitive to change with good predictive
311 validity for major depressive disorder [52]. Symptoms are rated from 0 (not present) to 6 (extreme
312 problems) and summed to form a total score (0-60). Research Assistants were trained in its use with
313 the accompanying interview guide (SIGMA [53]) prior to assessments with high inter-rater reliability
314 (ICC=.995 (p<.001), 95% CI .987-.999). Estimates for the minimal clinically important difference (MCID)
315 range from a 1.6-1.9 change from baseline with remission cut-off at <9 points [54-5]. Bandelow et al.,
316 found scores ≤5 are symptom free remission, ≤11 remission and a decrease in 39% from baseline
317 corresponded to ‘much improved’ on the clinical global impressions scale [56-7].

318 *Beck Depression Inventory II (BDI-II) [58]*

319 The BDI-II is a widely used self-reported 21-item measure of depression with good internal
320 consistency, sensitivity to change and established cutoffs for minimal (raw score <13), mild (14-19),
321 moderate (20-28) and severe (29-63) depression [58]. Items are rated on a scale of 0 (no problems) to
322 3 (extreme problems), and summed to form a total score (0-63). The estimated MCID is estimated at
323 either a reduction of 5 points [59-60] or a 30% reduction in total score [61], 17.5% reduction in scores
324 for depressed patients, and 32% for those with a longer duration and non-response to antidepressants
325 [62].

326 Secondary and exploratory outcomes

327 *Brief Symptom Inventory (BSI) [63]*

328 The BSI is a widely used 53-item self-report measure of psychological distress with good internal
329 consistency and established outpatient norms in both United States and UK samples [63-4]. Symptoms
330 are rated on a Likert scale from 0 (not at all) to 4 (extremely). There are nine subscales for symptom
331 clusters (0-4) and three global indices of distress; global severity index, positive symptom distress
332 index and positive symptom total, of which global severity is used as a single summary measure.

333 *Rosenberg self-esteem scale (RSES) [65]*

334 The RSES is a widely used 10-item self-report measure of self-esteem. Items are rated on a 4-point
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2 335 Likert scale from 'strongly agree' to 'strongly disagree'. Four items are reverse scored, and item totals
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4 336 are summed (0-40). The scale has good internal consistency (0.68-0.86) [66] and construct validity
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7 337 [67].
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10 338 *General Perceived Self-efficacy Scale (GPSES) [68]*
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13 339 The GPSES is a 10-item self-report measure of personal agency, rated on a 4-point Likert scale from
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15 340 'not at all true' to 'exactly true'. Item totals are summed (10-40). The scale has confirmed uni-
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18 341 dimensionality and good internal consistency (0.82-0.93) [68].
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21 342 *Client satisfaction questionnaire (CSQ) [69]*
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24 343 The CSQ measures self-reported satisfaction with services, and is rated on an 8-item scale from 1
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26 344 (dissatisfied) to 4 (very satisfied) and items summed (8-32). The scale is widely used in health
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29 345 services research and has good internal consistency (0.83-0.93)[69].
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32 346 *Work and social adjustment scale (WSAS) [70]*
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35 347 The WSAS is a self-report 5-item scale that measures the degree to which work and social life are
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37 348 impaired due to a health condition. Items are rated on an 8-point scale from 0 (not at all impaired) to
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40 349 8 (very severely impaired). Item totals are summed (0-40). The scale has demonstrated internal
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42 350 consistency (0.70 -0.94), and a test-retest correlation of 0.73 [70].
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45 351 *Manchester Short Quality of Life scale (MANSA)[71]*
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48 352 The MANSA is a 16-item self-report scale measuring satisfaction with different areas of life. Twelve
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51 353 items are rated on a 7-point Likert scale ranging from 1 ('couldn't be worse') to 7 ('couldn't be better')
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53 354 which are summed (12-84). Four items are dichotomous (yes/no) to indicate whether the person has
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55 355 a close friend, saw a friend in the last week, were accused of a crime or were a victim of physical
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58 356 violence. The scale has good internal consistency (0.74) and correlations of 0.83 and higher with the
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60 357 longer Lancashire Quality of Life Profile [71].
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358 *Life Skills Profile (LSP) [72]*

359 The LSP is an observer rated 39-item profile, originally designed for patients with schizophrenia.

360 Various domains of social functioning are rated on a 4-point scale from no difficulty (4) to considerable

361 difficulty (1). Items are summed into five subscales: self-care, non-turbulence, social contact,

362 communication and responsibility and overall functioning score (39-154). Internal consistency ranges

363 from 0.67-0.88 and the scale demonstrated good sensitivity to change in community patients with

364 chronic mental illness within an assertive outreach service [73].

365 *Level of hospitalisation*

366 Psychiatric hospital admissions, length of stay and readmissions were recorded from medical records

367 for the purposes of this study.

368 *Client services receipt inventory (CSRI) [74]*

369 The CSRI was used to collect information on face-to-face professional contacts, use of day care

370 services, contact with police, medications, time off work/college and receipt of state benefits.

371 *Process measures*

372 Within the treatment arm, process measures of mood and group relationships were administered

373 once per week pre- and post session. In addition, the BDI-II was completed post-session in week 3, 6,

374 9 and 12 of the intervention to track any self-reported changes in depression during the intervention

375 period. Attendance was logged by the therapist at every session, and reasons for non-attendance

376 recorded. Finally, qualitative end of therapy interviews were completed with participants in both

377 treatment and wait-list groups. These interviews were optional for participants.

378 *Dispositional Mood Scale (DMS) [75-6]*

379 The DMS is a self-report scale consisting of 20 adjectives describing current internal states.

380 Adjectives are rated on a scale of 1 (very slightly or not at all) to 5 (extremely) and summed as four

381 subscales of positive energy, tiredness, negative activation and relaxation. A further two-factor
382 solution is possible: 'Pleasant-Activation, Unpleasant Deactivation' and 'Unpleasant activation,
383 Pleasant deactivation'. Internal consistency varies between α : 0.83 - 0.93 [75].

384 *Relationship Satisfaction Scale (RSS) [77]*

385 The RSS is a 7-item self-report scale assessing the quality of a relationship. Items are rated on a 7-
386 point Likert scale from 0 ('very dissatisfied') to 6 ('very satisfied') and summed to form an overall
387 satisfaction score. The scale has not been validated, but assessed domains of relevance to group
388 relationships (eg. communication and openness, conflict resolution, intimacy and closeness).

389 *Music therapy group attendance*

390 Attendance was recorded by the music therapists every session on a pre-designed proforma,
391 including space to record reasons for non-attendance.

392 *Experience of therapy and research incorporating adapted Client Change Interview [50]*

393 A topic guide was pre-designed to enquire about experiences of both the therapy and taking part in
394 the study in qualitative interviews. For participants in the treatment arm, the Client Change
395 Interview [50] was used to explore helpful and hindering factors in therapy, changes experienced
396 during therapy and attributions for this.

397 *Adverse events*

398 Adverse events were recorded from the point of written informed consent to seven days post-
399 cessation of the study. Active monitoring commenced from the first point of attendance of group
400 music therapy to one week after the intervention finished. Expected adverse events were defined as:

- 401 • A participant exhibiting aggression (nonverbal or verbal behaviour)
- 402 • A participant causing harm to another person
- 403 • Disclosure of thoughts or plans which may place the individual or others at risk of harm.

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3 404 Serious adverse events that were defined for this study context included:

- 4 405 • A participant making a suicide attempt
- 5 406 • A participant causing life threatening injury to another
- 6 407 • An event occurring during the course of the study which resulted in hospitalisation or
- 7 408 prolongation of existing hospitalisation related to their mental health.

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13 409 Rationale for sample size

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16 410 Papers considering sample size for feasibility studies suggest inclusion of upwards of 24-50
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18 411 participants [78-80]. As the feasibility of our recruitment processes and sample were unknown, we
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20 412 based our sample size around what was practicable to provide within the study timeframe. We aimed
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22 413 to recruit 30 patients to participate in three groups of 10 patients in each. Participation rates in similar
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24 414 studies were between 25-33% of eligible patients consenting [81-3]. A sample size of 30 would allow
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26 415 us to estimate a participation rate of 25% to within 95% confidence interval of +/-15%. We estimated
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28 416 1300 patients would be eligible within primary care (assuming one fifth of those with current
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30 417 depression) and that each practice in the locality would therefore have around 20 with enduring
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32 418 symptoms. Secondary care services reported around 1960 patients with a diagnosis of depression,
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34 419 suggesting 392 would be potentially eligible for this study. Assuming a participation rate of 25% we
35
36 420 aimed to approach 128 patients, with the aim of recruiting 4 per week over 8-10 weeks.

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43 421 Randomisation

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45
46 422 To gain sufficient information regarding the intervention, we used an imbalanced design, randomising
47
48 423 20 participants to group music therapy and 10 to the wait-list control. We used simple block
49
50 424 randomisation once all 30 participants were recruited and baseline measures completed.
51
52 425 Randomisation was generated by a researcher independent to the study team, using the Experimental
53
54 426 Design Generator and Randomiser (EDGAR-II)[84]. One unblinded study team member and music
55
56 427 therapists were informed of the allocation, who then informed participants.

428 Blinding

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3 429 Researchers conducting assessments and the co-Chief Investigator (Priebe) were blinded to
4
5 430 participant allocation. Due to the trial design, participants, music therapists and the clinical teams
6
7
8 431 were not blinded to allocation. One Chief Investigator (Carr) and Clinical Studies Officers were
9
10 432 unblinded to enable communication with clinicians and administration of process measures.

11
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13 433 To maintain blinding of researchers, it was explained to participants on allocation that it was important
14
15 434 not to reveal this to the researcher who had conducted their assessments. Participants were reminded
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18 435 in every communication from researchers not to mention whether they had received music therapy
19
20 436 or not.

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23 437 Analysis

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26 438 For research methodology feasibility measures (objectives 1-4) we calculated screening, recruitment
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28
29 439 and drop-out rates, distributions of baseline characteristics and all outcomes one week, 3 and 6
30
31 440 months post-intervention. Clinical outcomes were analysed as intention-to-treat, using mean scores
32
33
34 441 for each group and 95% confidence intervals. We then used a mixed linear model, adjusting for
35
36 442 baseline scores of the given outcome and any significant baseline characteristics. The intra-cluster
37
38 443 correlation coefficient was calculated for group clustering. Adverse events were categorised and
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41 444 reported for each trial arm.

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44 445 For intervention feasibility measures (objective 6), we explored using descriptive statistics, any
45
46 446 differences between compliant/non-compliant attenders, responders and non-responders.
47
48
49 447 Qualitative interviews were analysed in two stages. In the first stage, participants who had received
50
51 448 music therapy were analysed to explore their experiences of the intervention and any changes
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53 449 (objective 6) using interpretative phenomenological analysis [85]. This enabled us to gain an in-depth
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56 450 understanding of participants' experiences during the songwriting groups including the meaning
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58 451 attributed by participants to their experiences. Further details of the analysis and findings are
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452 published in full elsewhere [85]. In a second stage, given the larger number of interviews and
453 predefined format of research procedures, comments relating to acceptability and experiences of
454 research procedures (objective 1) were analysed using deductive coding against each element of the
455 research design and then grouped to form a basic thematic analysis [86]. For health service use
456 (objective 7), hospitalisation and use of services were examined descriptively and compared between
457 groups.

458 Results

459 a) Feasibility and acceptability of research methodology (objectives 1-5)

460 Recruitment

461 Flow of participants in the study are shown in the Consolidated Standards of Reporting Trials
462 (CONSORT) diagram (Figure 1) and baseline characteristics in Table 3. A total of 421 patients were
463 screened and 235 potentially eligible participants identified. Reasons for exclusion at this stage were
464 not meeting the inclusion criteria (N=105), no clinician assent for contact (N=63), researchers unable
465 to make contact (N=25) or participants being deemed too unwell to approach (N=13) or unsuitable by
466 clinicians (N=5). Five were discharged from services before they could be approached. Of the 235
467 participants approached, 83 expressed interest with a participation rate (from potentially eligible
468 participants) of 12.7%. Forty-six declined while 146 were unable to contact or did not respond. One
469 GP practice participant expressed interest but was too late to join the study, and one self-referred
470 participant was too unwell to recruit within the study window. Whilst there were equivalent numbers
471 of potentially eligible participants within GP and Community Mental Health settings, recruitment was
472 most successful via Community Mental Health teams (CMHT) and self-referral from public
473 engagement events. The recruitment target was achieved, with 30 participants providing informed
474 consent over an eight week period and recruitment rate of 12.5% (Table 4). Recruitment was initially
475 slow with six participants recruited in the first four weeks and recruitment then peaking in weeks 5 (9

1 476 recruited) and 8 (5 recruited) (Table 4). Researcher time was adequate to cover the necessary
2 477 research tasks over the course of the study.
3
4

5 478 Baseline characteristics
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7

8 479 Participants were on average 44 years old, with the majority holding a diagnosis of recurrent
9
10 480 depressive disorder (ICD10 F33.0, 12/30 participants). Mean duration of diagnosis was 10.7 years
11
12
13 481 (range, 1-40 years). Few (3/30) had previously attended music therapy. Groups differed significantly
14
15 482 at baseline regarding gender (65% of the treatment arm were female compared to 30% in the wait-
16
17
18 483 list arm), self-efficacy, BSI scores and life skills of self-care and communication. The treatment arm
19
20 484 also had a greater proportion of participants with English as a second language. Depression symptom
21
22 485 severity had high variance, with participants scoring a large range of the MADRS (0-48), and BDI-II (1-
23
24
25 486 48). Two wait-list participants met the criteria for remission at baseline (<9) on the MADRS, while
26
27 487 seven met criteria for mild or moderate depression on the BDI-II (3 in treatment, 4 in wait-list).
28
29

30 488 <Insert Figure 1 here>
31
32

33 489 <Insert Table 3 here>
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35

36 490 <Insert Table 4 here>
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39 491 Retention
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41

42 492 Ten participants withdrew from the study between allocation and post-intervention with 60%
43
44 493 retention (n=18) at 6-month follow-up. On allocation, one wait-list participant withdrew due to no
45
46
47 494 longer being able to take part. The remaining nine withdrawals were in the treatment arm, of which
48
49
50 495 six did not attend any sessions. Those who did not attend withdrew from both study and intervention
51
52 496 due to being unable to commit to the group schedule (n=2), life events (n=2), symptom severity (n=1)
53
54 497 and loss of contact (n=1). Of those who did attend, one was withdrawn due to risk after the first
55
56
57 498 session, one felt that the study was not of benefit to depression after four sessions and one felt further
58
59 499 study participation was invalid having only attended three sessions and gained employment. At three
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1 500 months follow-up one further treatment participant who did not attend any sessions withdrew due
2 501 to too many other commitments and one wait-list participant due to commencing employment.
3
4 502 Outside of withdrawals, two separate losses to follow-up occurred, once at three months and once at
5
6
7 503 six months in the treatment arm.
8
9

10 504 Blinding

11
12
13 505 There were four instances of unblinding. One post-allocation, where an intervention participant called
14
15 506 the researcher to inform of the outcome; twice when arranging one week post-intervention
16
17
18 507 assessments with intervention participants and one wait-list participant at the six-month follow-up.
19
20 508 In the three cases of scheduling assessments, all were due to participants sharing upcoming
21
22 509 intervention-based appointments. With two blinded team members, there was capacity within the
23
24
25 510 research team to cover these assessments enabling all assessments to be completed with blinding
26
27 511 intact.
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30 512 Clinical outcomes

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33 513 Raw and adjusted outcomes are shown in Tables 5 and 6 respectively.
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35

36 514 <Insert table 6 here>
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39 515 <Insert table 6 here>
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41

42 516 Primary outcome – MADRS

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44
45 517 Groups differed at baseline (Treatment: 25.85, Waitlist: 19.20) with greater severity in the treatment
46
47
48 518 group. Measures indicated a worsening of symptoms in both groups post-intervention (Treatment
49
50 519 31.28; Waitlist 25.51), with the treatment group then improving to better than baseline at 3 and 6
51
52 520 month follow-ups (3 month 19.82; 6 month 24.91). The wait-list group scored higher than baseline
53
54
55 521 scores at 3 and 6 months (3 month: 23.51; 6 month 23.31). The intra-class correlation coefficient,
56
57 522 demonstrating the level of clustering between groups was 0.088.
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523 <Insert Figure 2 here>

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3 524 After adjusting for baseline scores, a change of greater than the MCID (-5.04, reduction of 20.2% from
4
5 525 baseline score) was seen at 3 months in the treatment group but not at one week or 6 months post-
6
7 526 intervention (Figure 2). Four participants in each arm saw reductions of more than 39%, equating to
8
9
10 527 'much improved' on the Clinical Global Impressions scale. For the four treatment participants this was
11
12 528 3 and 6 months post-intervention. For the four wait-list participants this was across all follow-up
13
14 529 timepoints. Three participants qualified for remission (scores less than 9): One participant in the
15
16 530 treatment arm (compliant attender) qualified as complete remission (<5) and two in the wait-list arm
17
18 531 (<9). Both the wait-list participants in remission withdrew from the study at the point of offer of music
19
20
21
22 532 therapy.

23 24 25 533 Secondary outcomes

26
27
28 534 Treatment group scores were worse compared to the wait-list group on all secondary measures one
29
30 535 week post-intervention apart from BSI Somatisation (Treatment: 2.08; Waitlist 2.09) and BSI Hostility
31
32 536 (Treatment 1.74; Waitlist 1.88). In the treatment group, mean difference improvements from baseline
33
34
35 537 to one week post-intervention were seen in self-efficacy (+0.88), LSP communication (+1.64) and BSI
36
37 538 subscales of somatisation (-0.36), interpersonal sensitivity (-0.18), depression (-0.17), anxiety (-0.24),
38
39
40 539 hostility (-0.82), phobia (-0.17), paranoia (-0.21), psychosis (-0.15), global severity (-0.17), positive
41
42 540 symptom totals (-1.05) and positive symptom distress (-0.22). In the wait-list group, all scales scored
43
44
45 541 worse in mean differences from baseline to one week post-intervention apart from LSP subscales of
46
47 542 non-turbulence (+0.05), social communication (+0.07), communication (+0.49) and responsibility
48
49 543 (+0.05).

50
51
52 544 At 3 months, treatment group scores were more favourable compared to the wait-list group on all
53
54 545 measures except the BDI-II (Treatment 30.72; Waitlist 29.60), CSQ (Treatment 21.46; Waitlist, 22.86)
55
56
57 546 and WSAS (Treatment 27.71, Waitlist, 27.07). The treatment group showed mean difference
58
59
60 547 improvements compared to baseline on all measures apart from CSQ (-2.69), WSAS (+0.86) and LSP

1 548 social contact (-0.97). The wait-list group showed mean difference deterioration compared to baseline
2 549 on all measures apart from satisfaction (+0.66), LSP non-turbulence (+1.94), LSP communication
3
4 550 (+0.04) and BSI Obsessive Compulsive subscale (-0.02).
5
6

7 551 At 6 months, scores favoured the treatment group on CSQ (Treatment, 22.56; Waitlist, 20.17), MANSA
8
9 552 (Treatment, 3.67; Waitlist 3.41), BSI sub-scales of somatisation (Treatment 1.73; Waitlist 1.78),
10
11 553 interpersonal sensitivity (Treatment 2.18, Waitlist, 2.28), depression (Treatment 2.42; Waitlist 2.57),
12
13 554 psychoticism (Treatment 2.56; Waitlist, 2.74) and LSP Self-Care (Treatment 35.82; Waitlist 33.06),
14
15 555 Non-turbulence (Treatment 45.46; Waitlist 44.89), Communication (Treatment 22.30, Waitlist, 22.22)
16
17 556 and LSP Sum score (Treatment 137.60; Waitlist 133.91). Mean difference change compared to baseline
18
19 557 was favourable on all measures apart from BDI-II (+3.08), Satisfaction (-1.59), Self-esteem (-2.25),
20
21 558 WSAS (+6.89) and BSI Obsessive-Compulsive (+0.51). Wait-list mean difference scores deteriorated
22
23 559 compared to baseline on all measures apart from the LSP sum score and subscales (LSP SUM +0.01).
24
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29 560 A negative MCID was detected one week post-intervention for the treatment arm after adjusting for
30
31 561 baseline scores in the BDI-II (gain of 5.26). A positive BDI-II MCID was detected in three treatment
32
33 562 group and four wait-list group participants via reduction of 5+ points, while two treatment and four
34
35 563 wait-list participants had reductions of >30%. Two treatment participants and five wait-list
36
37 564 participants met criteria for 'minimal' depression.
38
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41

42 565 Acceptability of research methodology to professionals and patients (objective 5)
43
44

45 566 End interviews with 10 participants and 7 clinical staff indicated generally good acceptability of the
46
47 567 research methodology and study procedures. Clinicians stated that the referral process had been easy.
48
49 568 Referrers were positive about the intervention being offered, particularly its intensity and
50
51 569 opportunities for socialisation and enjoyment. One suggested that it had been a reminder that more
52
53 570 was available than cognitive behavioural therapy (CBT). Patients declined participation mostly due to
54
55 571 not being interested or to the time commitment of attending groups. Clinicians valued researchers
56
57 572 being physically present in clinics to reduce delays between the study offer by the clinician and
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1 573 researcher contact. Written study information and weekly email reminders were appreciated
2 574 alongside prompt responses to clinical queries. The music therapists reported challenges in not
3
4 575 assessing participants prior to groups and suggested that group allocations post-intervention should
5
6
7 576 take into account individual characteristics beyond capacity to attend a morning or afternoon group.
8
9 577 There were further challenges as the music therapists worked across more than one clinical borough,
10
11 578 requiring rapid familiarisation with wider clinical teams. Similarly, where participants did not clearly
12
13
14 579 fall under a specific care pathway this led in some cases, to the music therapists having to case hold
15
16 580 whilst awaiting allocation to the relevant team. Music therapists reported joint working with the
17
18
19 581 research team as supportive especially when linking up for weekly process measures which often
20
21 582 provided further evidence to back up clinical concerns.

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24 583 Participants spoke positively about their experiences of participating in research even if their
25
26 584 experience in music therapy was less so. Some likened being invited to “winning the lottery”. Written
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29 585 materials were helpful as were consistent and clear communication. While waiting for the allocation
30
31 586 caused some apprehension, participants felt well-enough informed to accept that this was something
32
33
34 587 they had signed up to. Participants valued the relationships that they built with researchers and the
35
36 588 continuity of seeing the same person each time along with flexibility for appointments. They cited
37
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39 589 understanding, friendliness, support, encouragement to attend the next appointment and being
40
41 590 thanked for their time as important. The vouchers provided after assessments were welcomed and
42
43 591 cited as a good incentive to continue with research assessments. One participant suggested smaller
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45
46 592 denominations so that there was more flexibility in what could be purchased.

47 48 49 593 Acceptability of outcome measures

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51
52 594 Outcome measures were generally acceptable to participants with <1% of items missing. No items
53
54 595 were missing on the primary measure of the MADRS. Three participants struggled to answer CSQ
55
56
57 596 questions relating to services before they attended music therapy (eg. CSQ-B – Did you get the kind
58
59 597 of service you wanted?). A few participants declined to answer questions relating to sex (MANSA item

1
2 598 13, BDI-II item 21). Items 17, 18 (taking and accepting medication) and 25 (problems living with others)
3 of the LSP were most often rated as not applicable by researchers.

4
5 600 Some participants found the assessment questions anxiety provoking but the majority stated they
6 found them helpful and appreciated that they went into depth about current issues and provoked
7 reflection on how things were right now. The length of followup duration was also appreciated.
8 601
9
10 602 Participants who were less literate suggested that it was challenging to complete but that researchers
11 gave sufficient support in order to answer the questions. The most problematic assessment was the
12 LSP, which researchers found awkward to administer in a face to face interview. Introductory text was
13 added to explain the purpose of the questions to facilitate this. The CSRI also required updating when
14 participants noted that the benefits system had changed to those that were in the questionnaire.
15 603
16 604
17 605 Participants particularly appreciated the process measures which they stated helped them to notice
18 changes from week to week.
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30 610 Feasibility and acceptability of the intervention (objective 6)

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33 611 Compliance

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36 612 Mean attendance was 10.5 (SD 13.8) out of a possible 42 sessions (25%) with modes of 3 group
37 members per session in one group and 2 group members per session in the other. Participants split
38 into compliant (N=6, mean 27.8/66% sessions), non-compliant (n=8, mean 3.5/8% sessions) and non-
39 attenders (n=6). Five out of six compliant attenders had lower MADRS scores than noncompliant,
40 although one compliant attender scored the maximum (range 18-48) (Figure 6).
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48 617 Reasons for non-attendance linked directly to study withdrawal. Four participants with low baseline
49 MADRS scores (<15) withdrew early on. One wait-list participant who was recruited from a CMHT
50 scored 0 on the MADRS and withdrew prior to the one week post-intervention followup. Two were
51 participants recruited from Talking Therapies who both withdrew due to commencing employment
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621 (one having attended 3 sessions). One participant recruited from the CMHT withdrew due to childcare
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2 622 issues having attended one session.
3
4

5 623 Two out of the four participants recruited from GP practices did not attend despite scores of >30 on
6
7 624 the MADRS, one due to housing and carer issues and one due to loss of contact. The remaining four
8
9 625 non-attending participants had baseline MADRS scores ranging from 20-30 and did not attend due to
10
11 626 venue accessibility, worsening of symptoms, being unable to commit to the group and life events.
12
13

14
15 627 Of the eight non-compliant attenders, one was withdrawn to risk, two requested to withdraw from
16
17 628 the group due to group conflict and one left due to commencing employment. The remaining four
18
19 629 attended over the course of therapy but faced significant challenges due to refugee status, carer
20
21 630 responsibilities, homelessness and family illness.
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25 631 <Insert Figure 6 here>
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28
29 632 Based on low attendance figures, we opened up places to non-study participants for the wait-list
30
31 633 group. Two additional patients were offered places left by the two study withdrawals but did not
32
33 634 complete any study assessments or measures. One attended regularly and one did not attend due to
34
35 635 worsening of symptoms prior to the group starting. Of the wait-list study participants, attendance was
36
37 636 higher (mean 19.4/46%, SD 15.8) with mode of 5 participants per session. Five participants were
38
39 637 compliant (mean 30.8/73% sessions). One ceased attendance after a single session and lost contact
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41 638 with the research team, one after 6 sessions and one did not attend.
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45
46 639 Adherence
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49 640 Mean manual adherence was 44.45% (SD 25.94) with moderate reliability when coded by an
50
51 641 independent rater. The music therapists used all components of the manual over the course of the
52
53 642 groups but with different sections being used at particular times in the therapy process (for example,
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55 643 greater focus on introductory activities in early sessions, recording happening later on in the therapy
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644 process). In the two treatment groups, seven song recordings were made. One instrumental recording
645 and a number of improvisations were made in the wait-list group.

646 The music therapists suggested that further instruction on how to complete adherence forms would
647 have built their confidence alongside a different design of the forms that allowed for a less linear
648 approach to the group process.

649 Process measures

650 Due to low attendance, process measures of mood and relationship satisfaction were available for
651 only ten participants (morning group: 6/10, afternoon group: 4/10) and only six for depression (BDI-
652 II: morning group 3/10, afternoon group 3/10). Plots of pre and post mood scores (Figure 3) suggested
653 an increase in positive energy, relaxation and reduction in tiredness and negative activation in the
654 morning group alongside improvements in relationship satisfaction (Figure 4). The afternoon group
655 demonstrated a different picture whereby earlier sessions reported an increase in negative activation
656 and lower relationship satisfaction scores in the first four weeks and less marked mood differences
657 pre and post session. For the BDI-II (Figure 5), depression scores reduced in both groups between
658 weeks 3 and 6, but then increased again between weeks 6 and 9. There was a reduction in depression
659 in week 12 in the afternoon group.

660 <Insert Figure 3 here>

661 <Insert Figure 4 here>

662 <Insert Figure 5 here>

663 Experiences of the intervention

664 Ten participants took part in qualitative interviews. In terms of group experiences, three
665 superordinate themes were identified: The group as a happy and safe place; Music stimulates new
666 feelings and songwriting aids expression into words; Uncertainty, unmet needs and the ending were
667 challenging. Further detail on these experiences of the therapy can be found in Windle et al. [85].

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668 Participants reported an average of 5 changes (range 1-9) whilst referring clinicians reported observing
669 an average of three changes in their patients. The majority of these changes were positive, the most
670 common being linked to musical engagement, changes in mood and confidence. Three participants
671 reported increased engagement in other activities whilst three reported negative changes in terms of
672 nervousness, feeling worse at the end of therapy and becoming more housebound. Three of the
673 waitlist group participants reported changes they had hoped for, but did not happen, namely: a wish
674 to change memory of trauma, to change how they thought and a wish to have been more involved in
675 the group. Participants tended to be surprised by the changes that they had noticed (65% of changes
676 were rated as 4 or 5 on the Client Change Interview expectancy-surprised scale) and believed them to
677 be unlikely to have happened without therapy (58% of changes rated as 1 or 2 on the likelihood scale).
678 All participants rated their changes as moderately to extremely important (3-5 on the importance
679 scale).

680 Accessibility of the therapy location, session frequency and managing the group ending were
681 described as challenging by participants. Participants suggested longer sessions (eg. 2 hours) but twice
682 per week would be preferable to three times per week.

683 The music therapists reported challenges in the make-up of each therapy group alongside high levels
684 of drop-out and the impact on group members. Further attention to the make-up of the group was
685 suggested post-randomisation to ensure a good mix and balance of participants.

686 The music therapists spoke positively about the potential of group songwriting for this client group,
687 especially techniques of song sharing and combining check-ins and improvisation as a basis for
688 songwriting. They reported some challenges in group songwriting that were beyond their usual scope
689 of practice. Deciding how far to intervene in the songwriting process was described as challenging in
690 the beginning but they observed greater sophistication in the groups' ability to create over time.
691 Technology, whilst opening up new musical and recording possibilities was a challenge and they
692 suggested that the manual should include more on editing and recording processes.

693 Potential harms and unintended effects

694 A total of six adverse events (four in the treatment arm, two in the control) and one serious adverse
695 event (treatment arm) were reported during the study (Table 7) in seven different participants. All but
696 one (fainting during a research assessment) were expected events.

697 <Insert Table 7 here>

698 The most frequent adverse event was increased suicide risk, identified during the research
699 assessments. One participant disclosed a risk to self/others in a follow-up assessment which appeared
700 unrelated directly to the intervention but could possibly have been related to the recent ending of the
701 group. Within the treatment arm, events that occurred during the treatment phase included one
702 verbal threat and one increased suicide risk, identified during completion of process measures. The
703 verbal threat was assessed as probably unrelated given this participant's risk history although it is not
704 possible to say for certain if events in the group were a contributing factor. Two instances of
705 homelessness were also reported which, whilst not meeting the definition of an adverse event, were
706 reported as safeguarding alerts following local Trust policies.

707 Hospitalisation of one treatment arm participant happened during the follow-up assessment period
708 and was reported as a serious adverse event. This participant did not attend any group sessions and
709 withdrew without completing further assessments.

710 Health service use (objective 7)

711 Health service contacts reduced in both groups with a greater reduction in the treatment arm. There
712 were no further hospital admissions for mental health problems in either arm post-baseline. Third
713 sector contacts for self-help and leisure activities increased from baseline in the treatment arm one
714 week post-intervention and six months followup but were reduced at three months followup.

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3 717 Discussion

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5 718 This feasibility trial piloted a group songwriting music therapy intervention for patients with long-term
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7 719 depression and assessed the feasibility and acceptability of both the intervention and of conducting a
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9 720 larger randomised controlled trial. Descriptive information on health service use was collected to
10
11 721 inform a future health economic evaluation.

12
13 722 a) Feasibility and acceptability of research methodology

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15
16 723 The overall research methodology was feasible and acceptable. Recruitment was most successful in
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18 724 secondary care community mental health teams and via self-referrals from patient and public groups.
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20
21 725 Success may be due to the research team's familiarity recruiting in such services or potentially due to
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23 726 a higher threshold of symptom severity held by these services. Our approaches through GP practices
24
25 727 were by letter only and it remains to be seen if recruitment could have been more successful if
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27
28 728 researchers were available during clinic time to speak to those who express interest to their GP.
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31 729 Similarly, there was limited success in recruiting from Talking Therapy services, possibly due to lower
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33 730 symptom thresholds and recent receipt of talking therapy. Instances of unblinding were due to
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35 731 participants contacting researchers post-randomisation. Provision of a different contact telephone
36
37 732 number post-randomisation might help to manage communications and maintain blinding.

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39
40 733 In terms of clinical outcomes, there were differences between observer and self-reported measures
41
42 734 of depression. While participants did not report large changes between assessments, both blinded
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45 735 researchers and clinicians who were interviewed, reported wider observed changes. This may be due
46
47 736 to the chronicity of symptoms experienced by participants making it challenging to notice change (for
48
49
50 737 example, the BDI-II asks for changes in the last two weeks) [87]. We would therefore propose the
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52 738 MADRS as a suitable measure for the primary outcome of a future trial alongside secondary measures
53
54
55 739 of psychological distress, quality of life, and life skills.

1 740 Outcomes suggest a promising effect on the reduction of depression and improved social adjustment.
2
3 741 However, these improvements were not seen until 3 months post-intervention, suggesting this as the
4
5 742 point at which greatest improvement might be seen. Eight treatment participants and four waitlist
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7 743 participants scored worse for their depression symptoms at post-intervention. There are two possible
8
9 744 explanations. One is that for treatment participants, the ending of an intense social experience was
10
11 745 challenging and therefore measures picked up low mood for treatment participants at this endpoint.
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13 746 Further preparation, signposting and support of participants for their 'next steps' might help to
14
15 747 ameliorate this. Alternatively, the worsening of symptoms might be attributed to the time of year the
16
17 748 measures were taken as this occurred at the post-intervention followup which took place towards the
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19 749 end of January [88-9]. Finally, symptom improvements at the post-intervention follow-up in three
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21 750 wait-list arm participants may also capture their expectancy as they awaited to start their own groups
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23 751 [90], or they might capture spontaneous improvement.
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29 752 b) Feasibility and acceptability of intervention
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32 753 While overall elements of the intervention appeared feasible, a number of areas require modification
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34 754 prior to any further testing. Attendance was poor in treatment groups, but slightly better for the wait-
35
36 755 list group. A number of factors may help to explain this: Non-attending participants tended to either
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38 756 have a) low symptom severity scores (<15 on the MADRS), b) were recruited from Talking Therapies
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40 757 and commenced employment or c) felt there was too much going on to be able to commit to
41
42 758 attendance. Childcare, housing and multiple appointment demands were the main reasons cited for
43
44 759 being unable to commit. There was also a difference between morning and afternoon groups.
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46 760 Participants were given the option to choose which time they would prefer and noticeably, those with
47
48 761 more severe depression scores, chose the later time in the afternoon.
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54 762 The group frequency of 3 times per week was not feasible for this client group, hindered also for many
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56 763 by the group location. Participants suggested that twice per week would be more manageable in end
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58 764 interviews. Challenges in attendance are known for this patient population [91] and a number of
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1 765 participants faced significant issues with complex life situations including homelessness, care
2 766 responsibilities and safeguarding. Modifying the session duration and frequency might also mitigate
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4 767 the challenges faced at the end of treatment by participants and potentially improve outcomes at
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6
7 768 post-intervention. While the intervention included signposting of participants to wider community
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9 769 arts and social opportunities at the end of treatment, few participants attended these final sessions.
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11 770 It may therefore be important to arrange individual follow-up meetings post-intervention to review
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13 771 therapy progress and explore next steps.

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17 772 Process measures identified important elements of the group culture that may impact upon
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19 773 outcomes. The relationship satisfaction scale in particular gave a good indication of group cohesion
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21 774 and moments of conflict within the group. It may be that greater time was required in one group for
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23
24 775 the music therapists to foster trust and build a therapeutic relationship [9] prior to commencing the
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26 776 task of writing songs. It is known that early group cohesion is a predictor of later outcomes [92-3],
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28
29 777 thus these measures will be useful in explaining outcomes.

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32 778 The music therapists commented on the lack of control regarding group composition, resulting in
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34 779 groups with large differences in levels of musicianship and also groups where participants were
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36
37 780 already familiar with each other through other services. Neither of these variables were considered in
38
39 781 the trial, yet both critical mass and homogeneity of musical preferences are important factors in
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41 782 therapeutic group songwriting [94-5]. In a larger randomised controlled trial, it would be challenging
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44 783 to curate group composition post-randomisation as this would rely on sufficient recruitment up-front
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46 784 and may result in long delays between consent and commencement of the intervention. This poses a
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49 785 risk of attrition and potentially long waits for those who have enrolled onto the study as well as
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51 786 resource challenges in delivering a larger number of groups all together, rather than a more staggered
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53 787 approach [96].

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56 788 This study encountered issues in the music therapists' use of recording software as part of the
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58
59 789 intervention. Modifications to the intervention include more support for music therapists on editing

1 790 and recording songs within sessions and further skills training in the technology. Participants
2 791 suggested longer sessions of up to 2 hours would be beneficial to allow for these processes. The
3
4 792 adherence form also requires re-design to capture adherence to core group principles without relying
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6
7 793 upon a linear group process.
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10 794 c) Assessment of service use
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13 795 This was relatively simple to ascertain from participants although further patient and public
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15 796 involvement will be important to ensure benefits and related health economic questions are relevant
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18 797 and up to date.
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21 798 Consideration of intervention attendance and study withdrawals
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24 799 This study had a high number of withdrawals (N=12, 40%), most having occurred by the point of one
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26 800 week post-intervention. It was notable that all bar one of the non-attending participants in the
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28 801 treatment arm (N=5) chose to withdraw from the study despite encouragement to continue with
29
30 802 assessments. For these participants, elements of housing, caring and life made the thought of further
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32
33 803 participation too difficult. For the one participant who did not withdraw, contact was lost and the
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35
36 804 research team were unable to complete any of the follow-up assessments with this person. All other
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38 805 withdrawals were with participants who attended fewer than ten sessions. Further examination of the
39
40
41 806 factors preventing group attendance is therefore important prior to conducting a future trial. Group
42
43 807 attendance is known to be a challenge for this patient group [90] and strategies to address this include
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45 808 ensuring full information about the intervention, offering assessment or trial sessions and curating the
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48 809 location and time to be as accessible as possible. Further qualitative exploration with participants for
49
50 810 example, regarding barriers such as housing, appointments and childcare, may help to identify exactly
51
52 811 how and when group music therapy may be appropriate and accessible. Further stratification of
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54
55 812 patient characteristics may be useful in a larger trial [97]. For example, stricter eligibility criteria on
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57 813 depression severity (eg. a cut-off score of 20 on the MADRS) may help to avoid recruiting those with
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59 814 minimal depression scores who attend fewer sessions and it may also help to identify those who will
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1 815 struggle to attend due to a greater severity of symptoms and associated life factors. Recruitment may
2 816 be most successful from secondary care mental health services and this may also aid retention.
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4 817 Similarly, it will be important to balance randomisation on core characteristics of age, gender, duration
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6
7 818 of depression and symptom severity.
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10 819 Limitations

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13 820 The study is limited by necessarily small numbers, hence all outcomes are descriptive only and may
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15 821 not be representative of any true effect. The loss of follow-up data from those participants who
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17
18 822 withdrew and may not have benefitted from the intervention may similarly have impacted the
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20 823 outcomes reported. However, three out of four participants who withdrew from the intervention due
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22 824 to negative experiences or feeling there was not benefit still took part in assessments and were
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24
25 825 included in the outcome data. Recruitment was from one NHS site in East London and therefore
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27 826 findings may be limited in their generalisability to other settings.
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30 827 Conclusion

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33 828 Based on the study feasibility criteria, a randomised controlled trial of songwriting in group music
34
35 829 therapy is feasible and acceptable but further developments and modifications – especially to the
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38 830 intervention and also, the trial design are required.
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41 831 In terms of study design, recruitment should focus on community mental health teams, and link to
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43 832 patient and public forums. A recruitment rate of 4 patients per week can be expected, but time should
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45 833 be factored in to allow a slower recruitment rate at the start. Inclusion criteria should include
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47
48 834 screening for depression severity prior to informed consent. Randomisation should stratify for age,
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50 835 gender and duration of depression and include an active control to minimise any expectancy effect of
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53 836 treatment. Outcomes immediately post-intervention may be influenced by the treatment ending with
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55 837 benefits potentially detected at 3 months.
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1 838 Regarding the intervention, further piloting is required to refine the intervention and to determine
2 839 the primary end-point. Further intervention development is required to promote greater attendance
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4 840 and group cohesion. Introductory meetings, group location and transportation should be considered
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6
7 841 carefully. Groups should be less frequent with a longer course (eg. 2 per week over 6 months) and
8
9 842 require a critical mass of at least 4 members. More time is required to prepare for ending and after-
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11 843 care procedures.

13
14 844 Abbreviations

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16
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18 845 BDI-II: Beck Depression Inventory II

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21 846 BSI: Brief Symptom Inventory

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24 847 BSI ANX: BSI Anxiety subscale

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27 848 BSI DEP: BSI Depression subscale

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30 849 BSI GSI: BSI Global Severity Index

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33 850 BSI HOS: BSI Hostility subscale

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36 851 BSI IIS: BSI Interpersonal Sensitivity subscale

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39 852 BSI OC: BSI Obsessive-Compulsive subscale

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42 853 BSI PAR: BSI Paranoia subscale

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45 854 BSI PHOB: BSI Phobia subscale

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48 855 BSI PSDI: BSI Positive Symptom Distress Index

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51 856 BSI PST: BSI Positive Symptom Total

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54 857 BSI PSY: BSI Psychoticism subscale

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57 858 BSI SOM: BSI Somatisation subscale

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3 859 CI: Confidence interval
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6 860 CBASP: Cognitive behavioural analysis system of psychotherapy
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9 861 CBT: Cognitive behavioural therapy
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12 862 CD: compact disc
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15 863 CMHT: Community Mental Health Team
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18 864 CONSORT: Consolidated Standards of Reporting Trials
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21 865 CSQ: Client satisfaction questionnaire
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24 866 CSRI: Client services receipt inventory
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27 867 DMS: Dispositional Mood Scale
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30 868 EDGAR-II: Experimental Design Generator and Randomiser
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33 869 GP: General Practice
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36 870 GPSES: General Perceived Self-efficacy Scale
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39 871 HCPC: Health and Care Professions Council
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42 872 IAPT: Improving Access to Psychological Therapies
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45 873 ICD10: International Classification of Diseases and Related Health Problems (version 10)
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48 874 IPT: Interpersonal Psychotherapy
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51 875 LSP: Life Skills Profile
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54 876 LSP CAR: LSP Self-care subscale
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57 877 LSP COM: LSP Communication subscale
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60 878 LSP NON: LSP Non-turbulence subscale
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3 879 LSP RESP: LSP Responsibility subscale
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6 880 LSP SOC: LSP Social Contact subscale
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9 881 LSP SUM: LSP Sum score
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12 882 MANSAS: Manchester Short Quality of Life scale
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15 883 MADRS: Montgomery-Åsberg Depression Rating Scale
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18 884 MCID: Minimal clinically important difference
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21 885 NHS: National Health Service
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24 886 RSES: Rosenberg self-esteem scale
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27 887 RSS: Relationship Satisfaction Scale
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30 888 SD: Standard deviation
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33 889 UK: United Kingdom
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36 890 WSAS: Work and social adjustment scale
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39 891 Declarations
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42 892 Ethics approval and consent to participate
43
44 893 The study was given favourable ethical opinion by Wales – Research Ethics Committee 2 and approvals
45 894 granted by the Health Research Authority (IRAS project ID: 198964, REC reference:16/WA/0248). All
46
47 895 study participation was voluntary and written informed consent was sought prior to study
48
49
50 896 participation.
51
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53 897 Consent for publication
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56 898 Not applicable
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58
59 899 Availability of data and materials
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1 900 The datasets used and analysed for this study are available from the corresponding author on
2 901 reasonable request.

3
4
5 902 Competing interests

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7
8 903 The authors declare that they have no competing interests.

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23
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26
27 910 Authors' contributions

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29
30 911 CC conceived the study, participated in its design and coordination, analysed and interpreted the data
31
32 912 and drafted the manuscript. EM supported data collection, data analysis and drafting of the
33
34
35 913 manuscript. MD recruited participants, supported data collection and data entry. CB DW and JF were
36
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38
39 915 the study, participated in its design and conduct. All authors read and approved the final manuscript.

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22 934 a Professor of social psychiatry at Queen Mary University of London.
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8 1201 List of Figures
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11 1202 Figure 1. CONSORT diagram.
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14 1203 Figure 2. Estimated marginal means of MADRS and BDI-II outcome measures adjusting for baseline
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16 1204 score.
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19 1205 Figure 3. 4-Dimensional Mood and Subscales pre- and post-session, plotted by week and group.
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22 1206 Figure 4. Relationship Satisfaction scores pre- and post-session, plotted by week and group.
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25 1207 Figure 5. Depression scores on the BDI-II for whole sample and by group in weeks 3, 6, 9 and 12.
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28 1208 Figure 6: Scatter plot of baseline MADRS score and number of music therapy sessions attended by
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46 1214 Title of data: Music Therapy Song Writing Group Session Intervention Manual
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51 1216 diagram used in this study.
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1219 Table 1. TIDieR [47] summary of the Synchrony group music therapy with songwriting intervention

TIDieR Item	Description
1 Brief name	Synchrony group music therapy with songwriting for chronic depression
2 Why	<p>Chronic depression is associated with challenges with low mood, motivation and social isolation. Group formats may promote social integration, interaction, provide emotional and social support and offer potential cost-effectiveness [3, 29].</p> <p>Music therapy has promising evidence in treating depression [31] and offers a different therapeutic encounter. The intervention may be appealing and motivating encouraging attendance and engagement. Music has an immediate (often positive) impact upon mood [34] which may reduce symptom distress and within groups (especially singing), can promote social bonding [35]. Musical improvisation may support initial nonverbal communication of feeling states and aid patients in learning to name these [41]. Group songwriting may further aid verbal expression of internal experiences and is associated with improved quality of life [33]. Patient and carer groups value the accessibility of singing and importance of an 'end product' in promoting self-esteem, self-efficacy and achievement in recovery.</p> <p>By offering a regular intensive group format, patients will have opportunities to make music together thus providing opportunities to build trust and bond with others, improve mood and build relationships. We hypothesise this will lead to short-term reduction in psychological distress and improved social functioning. The above will contribute to improved self-esteem and self-efficacy and taken as a whole, a reduction in depression symptoms. Secondary impacts of reduced depression will be improved satisfaction with services, reduced impact of depression upon work and life and improved quality of life.</p>
3 What: materials	<ul style="list-style-type: none"> • Range of large and hand held percussion instruments eg. large: Djembe drum, bongos, conga, snare, tom toms / small: cabassa, castanets, cowbell, triangle, various shakers, chimes • Tuned instruments: guitar, electric keyboard and/or acoustic piano, auto harp, xylophone, ballaphone, marimba, glockenspiel, harmonica, thumb piano, chime bars, hand bells etc. • 2-4 microphones for recording and stand • Recording equipment: zoom digital audio recover, iPad with compatible external microphone and Garageband or similar software • Amplification for ipad and electric guitar/keyboard where required • Projector to connect to Ipad for song ideas • Speakers for playback • Flipchart and blu-tack
4 What: procedures	<p>Group music therapy with songwriting, based on an adapted songwriting intervention [33] and informed by psychodynamic music therapy for depression [40] and resource-oriented music therapy [36].</p> <ol style="list-style-type: none"> 1. Pre-therapy induction session with music therapists to meet each other, set expectations, answer questions and introduce the equipment and sorts of music-making that will happen.

	<ol style="list-style-type: none"> 2. Text message reminders sent to participants to encourage group attendance 3. First session: Extended introductions, overview of 14 week schedule, group rules, introduction to songwriting. 4. General group structure and format: Instrumental/body warm up and check in. Initial sessions use reflection on a piece of music brought to the session by a group member. Music therapists encourage group discussion. Warm-up improvisation using a theme from previous discussion to prepare for song-writing. Group reflection on the experience and ideas/themes they wish to take forward into the songwriting. Group songwriting with option to rehearse and/or perform elements. End of session check in on how feeling now compared to the beginning. Reflection on the group events and decisions. 5. Sessions 2-31: Songwriting and developing group song list 6. Sessions 32-42: Group review and closure – Sessions are dedicated to reviewing the songs written, including possibility to rehearse and record or perform. Reflection on group processes and relationships.
5 Provider	Two HCPC registered NHS music therapists.
6 How	Face to face, group format, up to 10 participants per group.
7 Where	Community centre, room with space to seat up to 12 (10 participants and 2 music therapists). Some décor such as paintings, plants, natural light. Reasonable soundproofing from interior to exterior. Room to be free from interruption or loud external noise for duration of session. Wifi to enable access to the internet for song-sharing and mobile phone signal.
8 When/how much	
a) Intensity	High intensity
b) Frequency	Three sessions per week.
c) Session time	90 minutes consisting of 60 minutes session with 15 minutes pre/post for socialisation.
d) Overall duration	14 weeks
9 Tailoring	Group structure was permitted to become more flexible (in terms of improvisation and songwriting content) as sessions progressed to tailor to the evolving needs of the group. Songwriting elements are used interchangeably where appropriate to aid the songwriting process (creating lyrics, developing the song, choosing genre, developing rhythmic structure, developing verse/chorus melody, choosing mode/harmony, adding instrumental accompaniment/possibilities for improvisation, rehearsing, final song performance).
10 Modifications	Participants unable to attend regularly were encouraged and supported to stay in contact with the music therapists and to return when they could. This meant some participants attended only once or twice per week, and some did not attend for an extended period in the group therapy. Songwriting was not used in the wait-list group.
11 How well: Planned fidelity strategies and assessment	Pre-designed fidelity check-list completed by music therapists every session. Observer-rated fidelity check-list completed by independent music therapist rater.
12 How well: Actual	Mean adherence of 44.45% (SD 25.94) with moderate reliability when coded by an independent rater. All manual components were used but with different sections occurring at different points in the therapy process.

1220 Table 2. Stop-go feasibility criteria

Outcome	Method	Success criteria				Timing
		Stop	Continue, modify protocol	Continue without modification but monitor closely	Continue without modifications	
Acceptability of methodology	Recruitment & retention rates as below					End of recruitment (week 8)
	Compliance	Mean attendance <10 sessions	Mean attendance <14 sessions	Mean attendance 14 sessions	Mean attendance 14+ sessions	End of int. (week 22)
	End interviews	Unfavourable views, serious concerns	Unfavourable views, suggestions for modification	Favourable views, suggestions for modification	Favourable views, no concerns	1 month post-intervention (week 26)
Feasibility of recruitment processes	Screening rates	Identify <50 potentially eligible subjects	Identify <100 potentially eligible subjects	Identify 100-128 potentially eligible subjects	Identify >128 potentially eligible subjects	End of recruitment
	Recruitment rates	Recruit <50% of sample size	N<25 in 8wks, <5% per week	N=25-30 in 8wks, <13% per week	N=30 in 8wks, 13% per week or greater	End of recruitment
	Participation rates	Participation rate <5%	Participation rate 5-15%	Participation rate 15-25%	Participation rate 25% or greater	6 months post-intervention
	Retention rates	Attrition >75%	Attrition 50-75%	Attrition 30-50%	Attrition <30%	6 months post-intervention
	End interviews	N/A	Major suggestions to improve recruitment processes	Minor suggestions to improve recruitment processes	No suggestions to improve expressed	1 month post-intervention (week 26)
Identify N eligible participants, participant rates and retention rates	N identified by HCPs	<50 identified	50-100 identified	100-128 identified	>128 potentially eligible identified	End of recruitment
	N expressing interest	<30 express interest	30-40 express interest	40-60 express interest	>60 express interest	End of recruitment
	N providing consent	<15 provide consent	15-25 provide consent	25-30 provide consent	30 provide consent	End of recruitment post-intervention, 3 and 6 months post-intervention
	N lost to follow-up	Attrition>75%	Attrition 50-75%	Attrition 30-50%	Attrition <30%	End of recruitment post-intervention, 3 and 6 months post-intervention
Researcher time and costs per participant	Researcher diary	N/A	Researcher time exceeds allocated time requiring additional study support	Researcher time and cost only just covers time required	Researcher time and cost fully covers time required	6 months post-intervention
Appropriate outcome measures	Variability of outcome Estimate of control mean and SD of change	No difference or clinically important difference favouring control detected based on confidence limits	Difference cannot be detected based on confidence limits but data suggests improvement favouring intervention	Difference can be detected based on confidence limits	Clinically important difference can be detected based on confidence limits	End of intervention
Intervention components	Therapist adherence End interviews	Adherence <50% Serious concerns expressed regarding intervention	Adherence <50% Major suggestions to adapt intervention	Adherence 50-75% Minor suggestions to adapt intervention	Adherence >75% No concerns or suggestions to adapt intervention	End of intervention

Intervention adherence	Therapist self-rated adherence Video rated adherence	Adherence <25%	Adherence 25-50%	Adherence 50-75%	Adherence >75%	End of intervention
Estimate of cost of intervention and services received	Therapist time CSRI	Cost significantly greater than usual care, no potential to modify intervention, no indication of benefits	Cost is greater than usual care – intervention may be modified, but outcomes suggest some benefits	Cost is greater than usual care but outcomes strongly suggest benefits.	Cost is equivalent to or slightly greater than usual care, outcomes strongly suggest benefits	6 months post-intervention

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13 1222 Table 3. Baseline socio-demographic and clinical characteristics

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Baseline Characteristics	Treatment Group (n=20)	Waitlist Group (n=10)	Total (n=30)
Age	42.25 (37.09, 47.41)	48.8 (42.07, 55.53)	44.43 (40.39, 48.47)
Females:Males ^a	13:7	3:7	16:14
English First language:Second language	10:10	8:2	18:12
In Employment:Unemployed	4:16	1:9	5:25
Primary Diagnosis:			
F31	5/20	1/10	6/30
F32	3/20	2/10	5/30
F33	7/20	5/10	12/30
F41	3/20	0/10	3/30
F43	2/20	2/10	4/30
Duration Diagnosis (years)	9.80 (4.37, 15.23)	12.5 (4.14, 20.86)	10.70 (6.41, 15.00)
Hospitalised in the last year	6/20	1/10	7/30
Medication			
Antidepressants	13/20	6/10	19/30
SNRI	4/20	1/10	5/30
TCA	6/20	0	6/30
NASSA	5/20	0	5/30
SSRI	4/20	5/10	9/30

Antipsychotic	14/20	3/10	17/30
Atypical	13/20	3/10	16/30
Typical	1/20	0	1/30
Hypnotics/Anxiolytics	7/20	2/10	9/30
Benzodiazapine	1/20	0	1/30
Antihistamine	5/20	1/10	6/30
Hypnotic	1/20	1/10	2/30
Mood stabilisers	2/20	1/10	3/30
No psychiatric medication	3/20	3/10	6/30
Previous receipt of music therapy	1/20	2/10	3/30
Interest in Music -ve	3.3 (2.74, 3.87)	2.85 (2.24, 3.46)	3.15 (2.74, 3.56)
Interest in Music +ve	3.35 (3.03, 3.68)	3.65 (3.13, 4.17)	3.45 (3.19, 3.71)
MADRS	25.85 (21.61, 30.09)	19.2 (10.73, 27.67)	23.63 (19.76, 27.50)
BDI II	30.92 (25.69, 36.15)	23.56 (13.35, 33.77)	28.47 (23.78, 33.15)
CSQ	24.15 (21.57, 26.73)	22.20 (17.92, 26.48)	23.5 (21.39, 25.61)
MANSA	3.64 (3.20, 4.07)	4.03 (3.44, 4.61)	3.77 (3.43, 4.10)
RSES	22.3 (20.21, 24.59)	24.2 (20.67, 27.73)	22.93 (21.20, 24.67)
GPSES ^b	22.05 (18.97, 25.13)	26.4 (23.27, 29.53)	23.5 (21.18, 25.82)
WASAS	26.85 (23.03, 30.67)	21.80 (13.22, 30.38)	25.17 (21.54, 28.79)
BSI Somatisation ^e	2.44 (2.06, 2.81)	1.15 (0.53, 1.78)	2.00 (1.63, 2.39)
BSI Obsessive-Compulsive	2.65 (2.31, 2.99)	2.19 (1.54, 2.84)	2.50 (2.19, 2.80)
BSI Interpersonal Sensitivity ^f	2.46 (2.07, 2.85)	1.28 (0.55, 2.00)	2.06 (1.68, 2.45)
BSI Depression ^g	2.67 (2.27, 3.07)	1.81 (1.03, 2.58)	2.38 (2.00, 2.76)
BSI Anxiety ^h	2.31 (1.95, 2.68)	1.44 (0.80, 2.07)	2.02 (1.68, 2.36)
BSI Hostility ⁱ	2.56 (2.06, 3.05)	1.68 (1.25, 2.12)	2.27 (1.89, 2.64)

BSI Phobia ^j	2.51 (2.18, 2.83)	1.42 (0.47, 2.36)	2.14 (1.75, 2.54)
BSI Paranoia ^k	2.52 (1.99, 3.06)	1.77 (1.21, 2.33)	2.27 (1.86, 2.67)
BSI Psychoticism	2.72 (2.26, 3.19)	2.01 (1.25, 2.77)	2.49 (2.09, 2.88)
BSI Global Severity Index ^l	2.04 (1.65, 2.44)	1.12 (0.59, 1.66)	1.74 (1.39, 2.08)
BSI Positive Symptom Total ^m	39.90 (34.86, 44.94)	29.20 (20.27, 38.13)	36.33 (31.75, 40.91)
BSI Positive Symptom Distress Index ⁿ	2.58 (2.27, 2.91)	1.85 (1.39, 2.30)	2.34 (2.06, 2.62)
LSP Self Care ^c	32.2 (30.48, 33.92)	35.2 (32.89, 37.51)	33.2 (31.80, 34.61)
LSP Non-turbulence	40.30 (36.75, 43.85)	42.70 (40.59, 44.81)	41.1 (38.69, 43.51)
LSP Social Contact	14.90 (13.27, 16.54)	15.60 (13.01, 18.20)	15.13 (13.83, 16.44)
LSP Communication ^d	20.05 (18.71, 21.39)	22.10 (21.12, 23.08)	20.73 (19.75, 21.71)
LSP Responsibility	17.35 (16.04, 18.66)	18.30 (16.72, 19.88)	17.67 (16.69, 18.64)

^a Wilcoxon-Mann-Whitney, $z=-2.096$, $p=.04$ ^bTwo-tailed t-test, unequal variances assumed, $p=.04$; ^cTwo-tailed t-test, unequal variances assumed, $p=.03$; ^{d-n}Two-tailed t-test, unequal variances assumed, ^d $p=.01$; ^e $p<.01$; ^f $p<.01$; ^g $p=.05$; ^h $p=.02$ ⁱ $p<.01$; ^j $p=.03$; ^k $p=.05$; ^l $p<.01$; ^m $p=.03$; ⁿ $p<.01$;

Baseline data: mean (95% confidence interval)

1235 Table 4. Weekly recruitment rates

Week	N recruited	Cumulative total	Weekly Percentage	Cumulative percentage
1	0	0	0%	0%
2	1	1	3%	3%
3	3	4	10%	13%
4	2	6	7%	20%
5	9	15	30%	50%
6	6	21	20%	70%
7	3	24	10%	80%
8	6	30	20%	100%

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1237 Table 5. Raw outcomes post-intervention, 3 and 6 months post-interventions

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Table 5. Raw outcomes post-intervention, 3 and 6 months post intervention.

	Post-intervention Raw Scores						3 Month Raw Scores						6 Month Raw Scores					
	Treatment group N=10			Waitlist group N=9			Treatment group N=9			Waitlist group N=9			Treatment group N=10			Waitlist group N=8		
	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI	Mean	SD	95%CI
MADRS	33.60	8.91	27.23, 39.97	23.44	13.89	12.76, 34.12	21.67	9.12	14.65, 28.68	21.44	12.08	12.16, 30.73	25.70	8.98	19.27, 32.13	22.00	10.81	12.96, 31.04
BDI-II	39.18	8.32	33.23, 45.13	25.29	11.43	16.51, 34.07	33.78	15.08	22.18, 45.37	26.28	11.89	17.14, 35.41	35.70	13.81	25.82, 45.58	26.89	14.50	14.77, 39.01
CSQ	21.80	6.11	17.43, 26.17	20.78	6.65	15.67, 25.89	22.22	8.06	16.03, 28.42	22.22	6.74	17.04, 27.40	23.60	8.68	17.39, 29.81	18.88	5.59	14.20, 23.55
MANSA	2.90	0.85	2.29, 3.51	3.95	0.97	3.21, 4.70	3.43	1.22	2.49, 4.36	4.07	1.03	3.28, 4.86	3.24	0.85	2.63, 3.85	3.86	1.47	2.63, 5.08
RSES	18.20	4.98	14.63, 21.77	23.78	4.09	20.64, 26.92	22.22	7.61	16.37, 28.07	24.67	4.72	21.04, 28.29	21.10	7.61	15.66, 26.54	25.13	5.57	20.47, 29.78
GPSES	21.50	8.13	15.69, 27.31	26.11	4.31	22.80, 29.43	24.56	7.97	18.43, 30.68	26.22	4.79	22.54, 29.90	22.30	7.20	17.15, 27.45	24.13	5.38	19.62, 28.63
CVSAS	31.10	6.08	26.75, 35.45	21.56	10.56	13.44, 29.67	30.22	11.51	21.38, 39.07	23.67	9.21	16.59, 30.74	30.60	4.72	27.22, 33.98	22.50	10.31	13.88, 31.12
BSI SOM	2.67	0.88	2.04, 3.30	1.50	0.74	0.94, 2.07	1.86	1.08	1.03, 2.69	1.46	0.70	0.92, 2.00	2.10	1.00	1.39, 2.82	1.32	0.69	0.75, 1.90
BSI OC	3.02	0.82	2.44, 3.61	2.13	0.72	1.57, 2.68	2.59	1.03	1.80, 3.39	2.01	0.84	1.37, 2.66	2.78	0.78	2.22, 3.34	2.21	0.91	1.45, 2.97
BSI IP	2.93	0.85	2.32, 3.53	1.62	1.00	0.85, 2.39	2.68	1.13	1.81, 3.54	2.25	0.81	1.63, 2.87	2.58	0.99	1.87, 3.28	1.80	0.96	1.00, 2.60
BSI DEP	2.98	0.94	2.31, 3.65	1.88	1.11	1.02, 2.73	2.84	1.17	1.94, 3.74	2.16	0.93	1.45, 2.88	2.74	1.15	1.91, 3.56	2.19	0.97	1.38, 3.00
BSI ANX	2.40	0.71	1.89, 2.91	1.57	0.97	0.83, 2.32	2.16	1.20	1.23, 3.08	1.87	0.79	1.27, 2.48	2.36	0.81	1.78, 2.94	1.71	0.71	1.12, 2.31
BSI HOS	2.12	0.93	1.45, 2.79	1.51	1.16	0.62, 2.40	2.01	1.09	1.16, 2.85	1.70	0.79	1.09, 2.31	2.25	1.04	1.50, 2.99	1.49	0.93	0.71, 2.27
BSI PHO	2.76	0.64	2.31, 3.22	1.49	1.16	0.60, 2.38	2.48	1.09	1.64, 3.32	1.55	1.08	0.72, 2.39	2.52	1.05	1.76, 3.27	1.74	0.97	0.93, 2.55
BSI PAR	2.81	0.85	2.20, 3.42	1.69	0.62	1.22, 2.17	2.78	0.90	2.09, 3.47	1.90	0.72	1.34, 2.46	2.68	0.87	2.06, 3.30	1.75	0.82	1.06, 2.44
BSI PSY	3.03	0.87	2.41, 3.65	1.89	1.25	0.93, 2.85	2.99	1.27	2.02, 3.96	1.80	1.15	0.91, 2.68	2.91	0.90	2.26, 3.55	2.36	1.09	1.45, 3.28
BSI GSI	2.41	0.79	1.85, 2.97	1.25	0.73	0.68, 1.81	2.15	0.91	1.45, 2.85	1.29	0.73	0.73, 1.85	2.28	0.87	1.66, 2.90	1.31	0.68	0.74, 1.88
BSI PST	44.40	7.46	39.07, 49.73	31.89	13.01	21.89, 41.89	40.44	15.23	28.74, 52.15	32.78	10.99	24.33, 41.22	44.20	12.79	35.05, 53.35	33.38	11.39	23.85, 42.90
BSI PSDI	2.80	0.73	2.28, 3.32	1.92	0.51	1.52, 2.31	2.61	0.71	2.06, 3.16	1.94	0.64	1.44, 2.43	2.62	0.67	2.14, 3.09	1.95	0.70	1.36, 2.54
LSP CAR	30.30	2.95	28.19, 32.41	34.44	3.50	31.75, 37.14	34.44	2.83	32.27, 36.62	34.33	3.43	31.70, 36.97	35.30	2.11	33.79, 36.81	33.75	3.69	30.66, 36.84
LSP NON	38.80	5.33	34.99, 42.61	43.00	2.18	41.32, 44.68	43.67	3.81	40.74, 46.59	44.89	2.62	42.88, 46.90	45.40	2.27	43.78, 47.02	45.13	3.27	42.39, 47.86
LSP SOC	13.50	4.93	9.98, 17.02	15.44	4.48	12.00, 18.88	14.56	4.82	10.85, 18.26	14.56	5.17	10.58, 18.53	15.90	4.12	12.95, 18.85	15.13	4.42	11.43, 18.82

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17																				
18	LSP COM	21.40	2.01	19.96, 22.84	22.78	1.20	21.85, 23.70	22.22	1.92	20.74, 23.70	22.33	1.22	21.39, 23.27	22.20	0.92	21.54, 22.86	22.38	1.60	21.04, 23.71	
19																				
20	LSP RES	16.40	1.58	15.27, 17.53	18.44	1.01	17.67, 19.22	18.44	1.59	17.22, 19.67	17.67	1.41	16.58, 18.75	18.20	2.04	16.74, 19.66	18.50	1.20	17.50, 19.50	
21																				
22	LSP SUM	120.4	8.28	114.5, 126.3	134.11	10.14	126.3, 141.9	133.3	9.72	125.9, 140.8	133.8	9.88	126.2, 141.4	137.0	6.43	132.4, 141.6	134.9	9.20	127.2, 142.6	

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Table 6. Outcomes post-intervention, 3 and 6 months post-intervention adjusted for baseline characteristics

	Post intervention						3 months						6 months					
	Treatment group N=10			Waitlist group N=9			Treatment group N=9			Waitlist group N=9			Treatment group N=10			Waitlist group N=8		
	Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI		Mean	95% CI	
MADRS	31.28	25.03	37.53	25.51	18.95	32.08	19.82	13.36	26.28	23.51	17.04	29.98	24.91	18.79	31.03	23.31	16.46	30.16
BDI-II	35.87	30.03	41.71	28.61	22.46	34.75	30.72	22.97	38.48	29.60	21.83	37.36	34.08	27.30	40.85	29.03	21.45	36.62
CSQ	21.36	17.48	25.24	21.41	17.31	25.51	21.46	16.84	26.08	22.86	18.24	27.47	22.56	17.69	27.43	20.17	14.71	25.62
MANSA	3.35	2.87	3.83	3.43	2.92	3.94	3.89	3.59	4.20	3.55	3.24	3.85	3.67	3.19	4.16	3.41	2.87	3.96
RSES	19.45	17.53	21.37	22.31	20.28	24.34	23.73	21.17	26.28	23.20	20.65	25.75	21.95	19.45	24.46	24.10	21.30	26.90
GPSES	22.93	20.14	25.72	25.01	22.07	27.95	25.20	22.44	27.96	25.12	22.35	27.88	22.94	20.52	25.37	23.29	20.58	26.01
WSAS	27.82	24.20	31.44	24.96	21.14	28.77	27.71	21.59	33.83	27.07	20.92	33.22	28.69	24.94	32.45	24.16	19.98	28.34
BSI SOM	2.08	1.65	2.51	2.09	1.64	2.54	1.36	0.81	1.90	2.04	1.49	2.60	1.73	1.29	2.17	1.78	1.29	2.28
BSI OC	2.84	2.36	3.32	2.28	1.78	2.78	2.47	1.91	3.04	2.17	1.60	2.74	2.70	2.20	3.21	2.33	1.76	2.89
BSI IIS	2.28	1.87	2.68	2.26	1.84	2.68	2.15	1.44	2.85	2.89	2.18	3.59	2.18	1.89	2.46	2.28	1.96	2.60
BSI DEP	2.50	2.03	2.96	2.37	1.88	2.87	2.40	1.84	2.97	2.66	2.09	3.23	2.42	1.97	2.86	2.57	2.07	3.06
BSI ANX	2.07	1.66	2.47	1.84	1.41	2.26	1.96	1.35	2.56	2.14	1.53	2.75	2.24	1.89	2.59	1.92	1.53	2.31
BSI HOS	1.74	1.24	2.24	1.88	1.35	2.40	1.71	1.29	2.14	2.07	1.64	2.50	2.00	1.44	2.56	1.77	1.15	2.40
BSI PHOB	2.34	2.01	2.67	1.89	1.55	2.24	2.14	1.67	2.60	1.96	1.49	2.43	2.25	1.84	2.66	2.09	1.63	2.55
BSI PAR	2.31	1.90	2.73	2.16	1.73	2.60	2.36	2.04	2.68	2.37	2.05	2.69	2.39	2.11	2.67	2.15	1.83	2.47
BSI PSY	2.57	2.13	3.01	2.39	1.92	2.85	2.56	2.02	3.11	2.29	1.75	2.84	2.56	2.18	2.94	2.74	2.32	3.16
BSI GSI	1.87	1.57	2.17	1.77	1.45	2.08	1.71	1.36	2.05	1.82	1.47	2.16	1.95	1.69	2.21	1.73	1.44	2.02
BSI PST	38.85	34.16	43.53	38.21	33.25	43.17	35.37	30.12	40.62	39.10	33.80	44.40	39.73	35.06	44.39	37.40	32.21	42.59
BSI PSDI	2.37	2.12	2.62	2.31	2.05	2.57	2.27	2.00	2.54	2.33	2.06	2.60	2.39	2.17	2.60	2.27	2.03	2.51
LSP CAR	31.11	29.15	33.06	33.67	31.62	35.73	35.12	33.68	36.57	33.56	32.11	35.01	35.82	34.05	37.60	33.06	31.08	35.05

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LSP NON	39.18	36.86	41.50	42.75	40.31	45.19	43.89	42.12	45.66	44.64	42.87	46.42	45.46	43.26	47.66	44.89	42.43	47.35
LSP SOC	13.45	11.56	15.33	15.67	13.68	17.66	13.93	11.37	16.49	14.78	12.22	17.34	15.47	13.34	17.59	15.93	13.56	18.31
LSP COM	21.69	20.53	22.85	22.59	21.37	23.81	22.31	21.41	23.22	22.14	21.24	23.05	22.30	21.55	23.04	22.22	21.39	23.06
LSP RESP	16.52	15.69	17.34	18.35	17.49	19.22	18.50	17.56	19.45	17.57	16.63	18.52	18.26	17.01	19.52	18.42	17.02	19.83
LSP SUM	122.34	117.45	127.23	132.68	127.55	137.81	134.23	129.26	139.20	132.34	127.36	137.33	137.60	132.12	143.08	133.91	127.78	140.05

Table 7. Adverse events and classification by treatment arm

Event	Classification	During treatment	During follow-up assessments	Treatment N=20	Control N=10	Expected?	Related?
Verbal threat	Adverse Event	1	0	1	0	Expected	Probably unrelated
Increased suicide risk	Adverse Event	1*	2	2	1	Expected	Unrelated
Disclosure of risk to self/others	Adverse Event	0	1	1	0	Expected	Probably unrelated
Hospitalisation	Serious Adverse Event	0	1	1**	0	Expected	Unrelated
Faint during research assessment	Adverse Event	0	1	0	1	Unexpected	Unrelated
Homelessness	Safeguarding alert	2	0	2	0	Unexpected	Unrelated
Total Number of events		4	5	7	2		

*Risk identified during research assessment after the therapy group

**Participant did not attend any group sessions

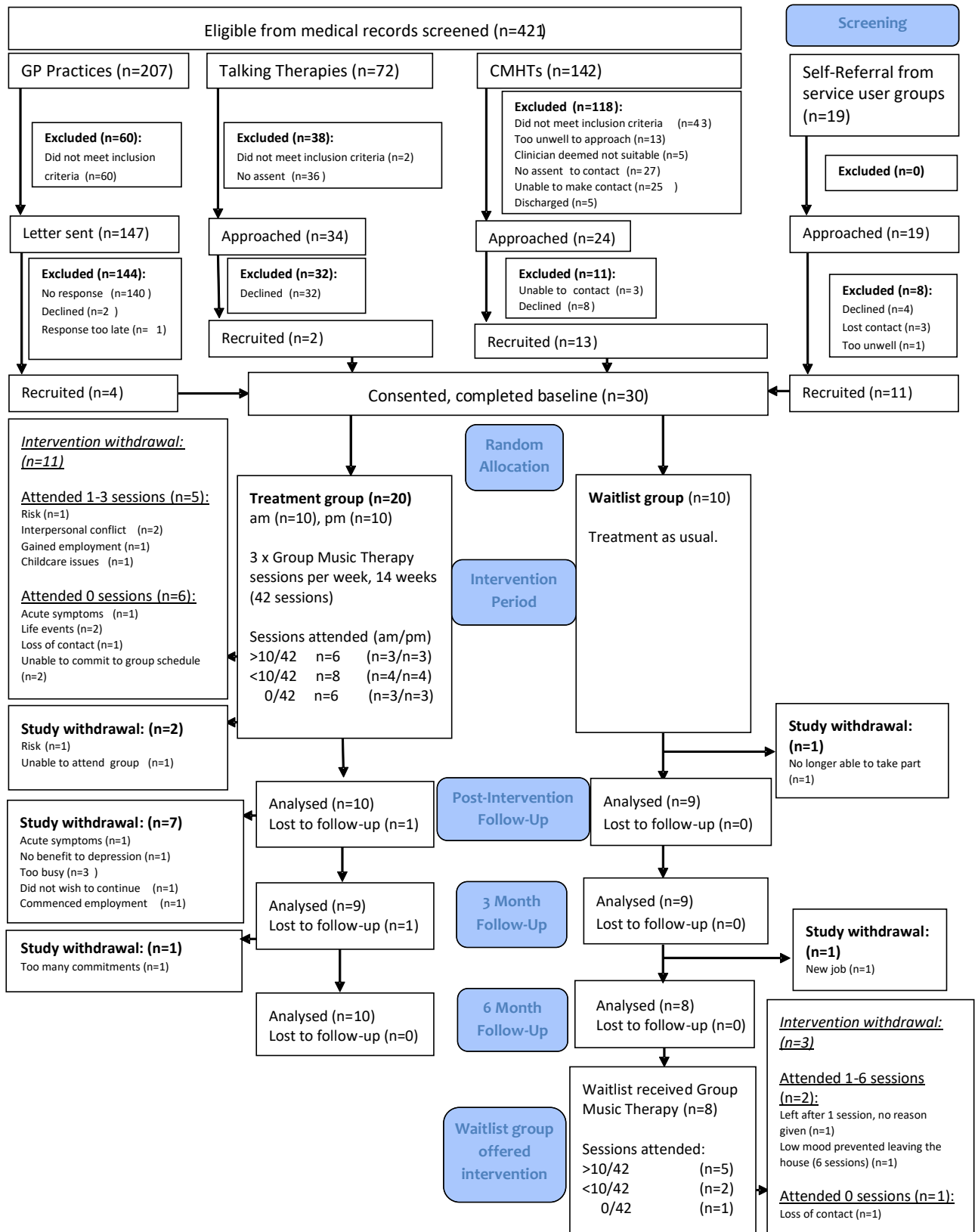
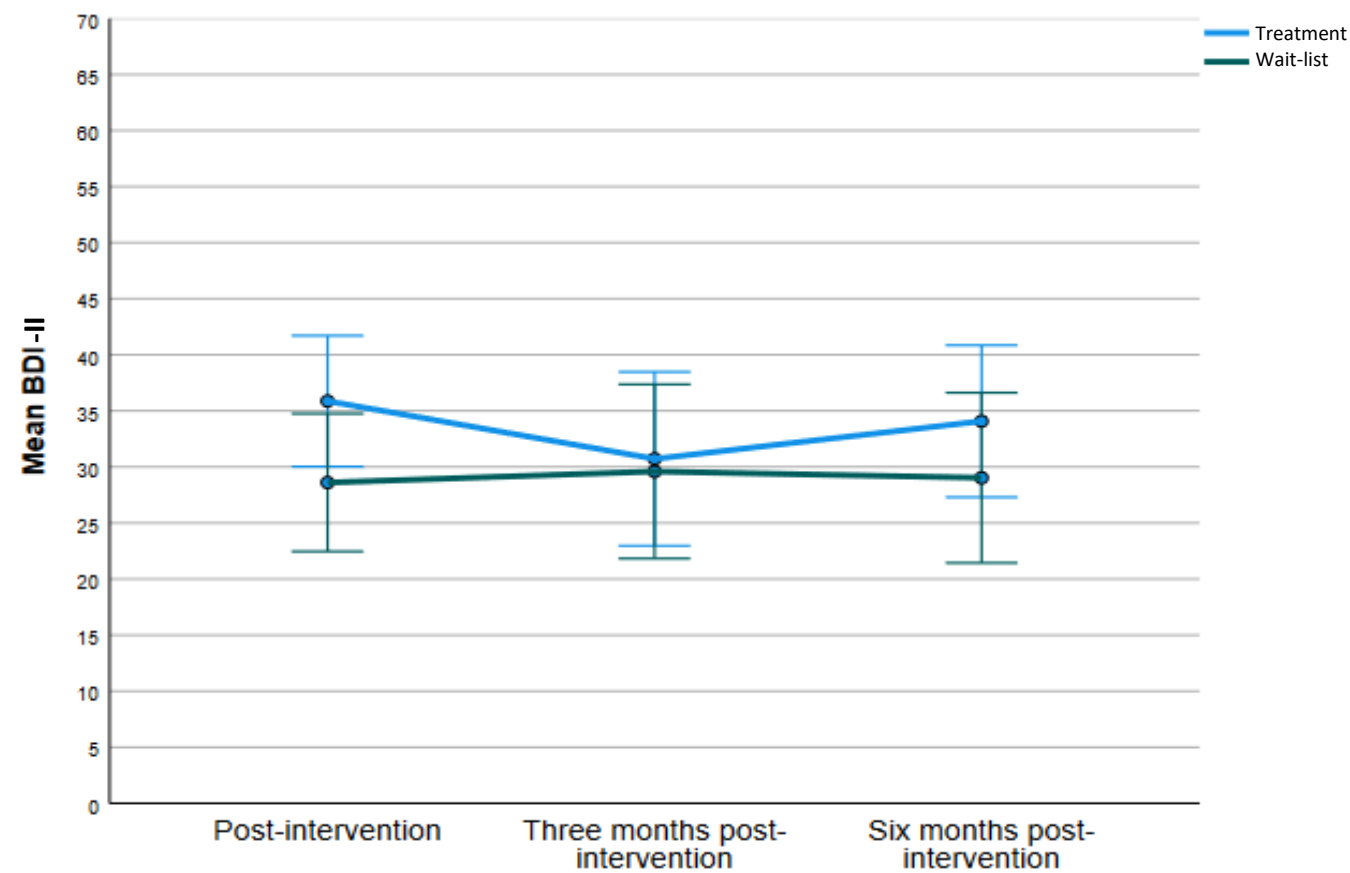
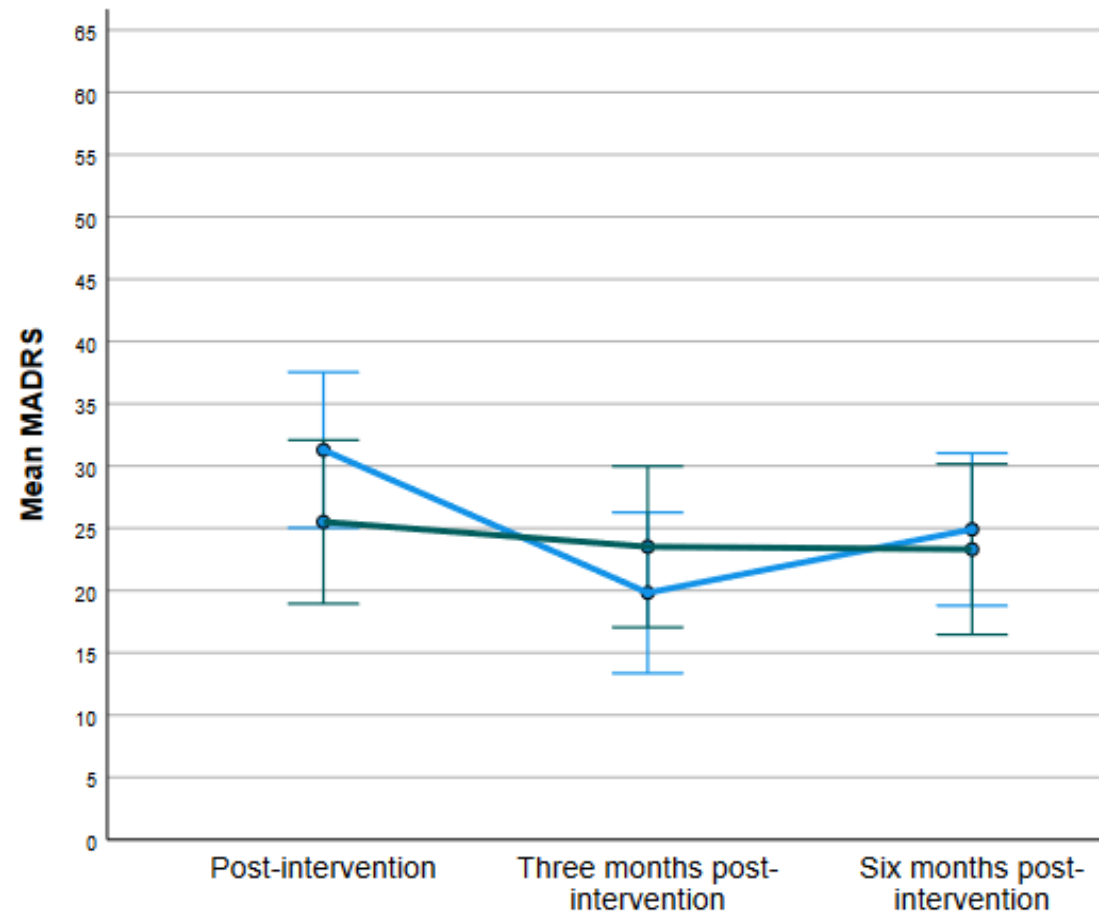
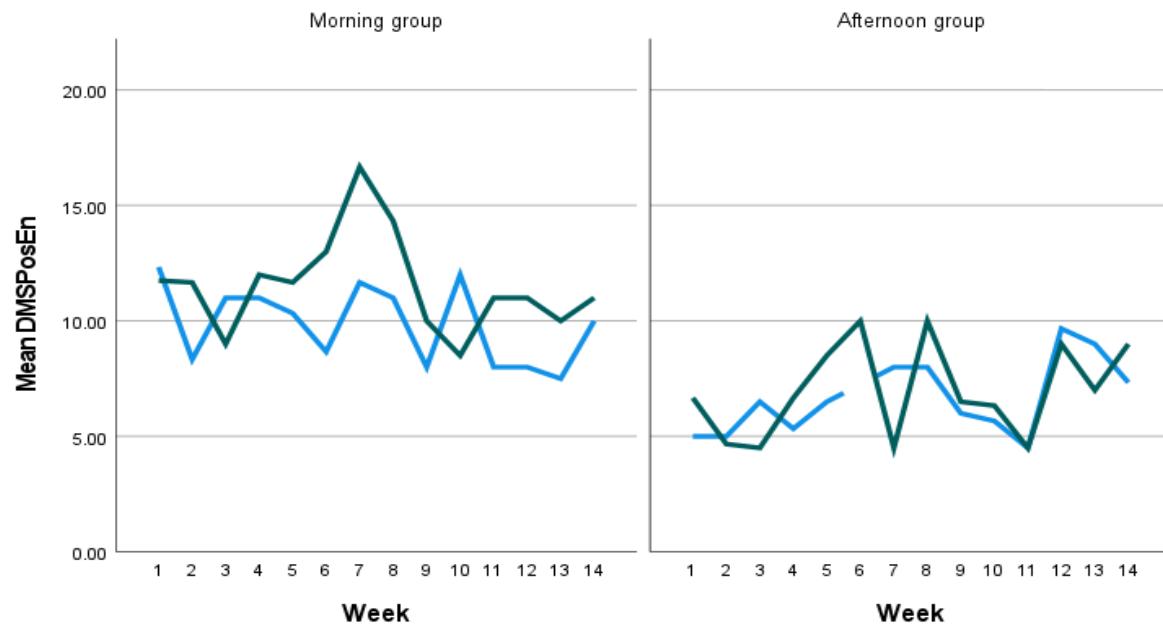


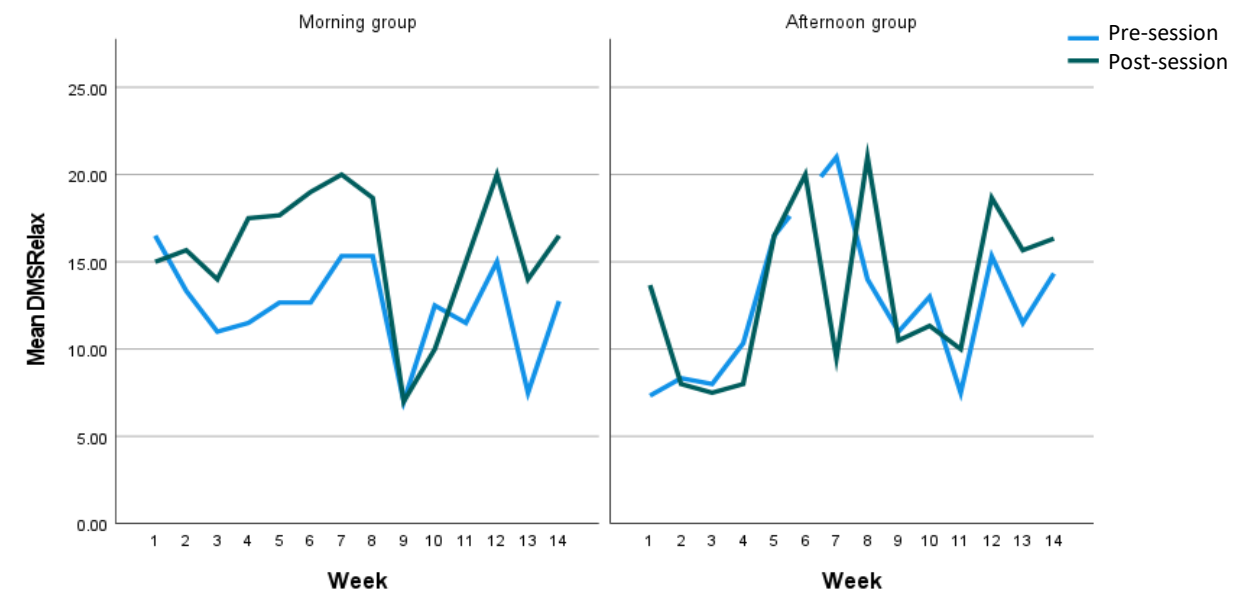
Figure 2



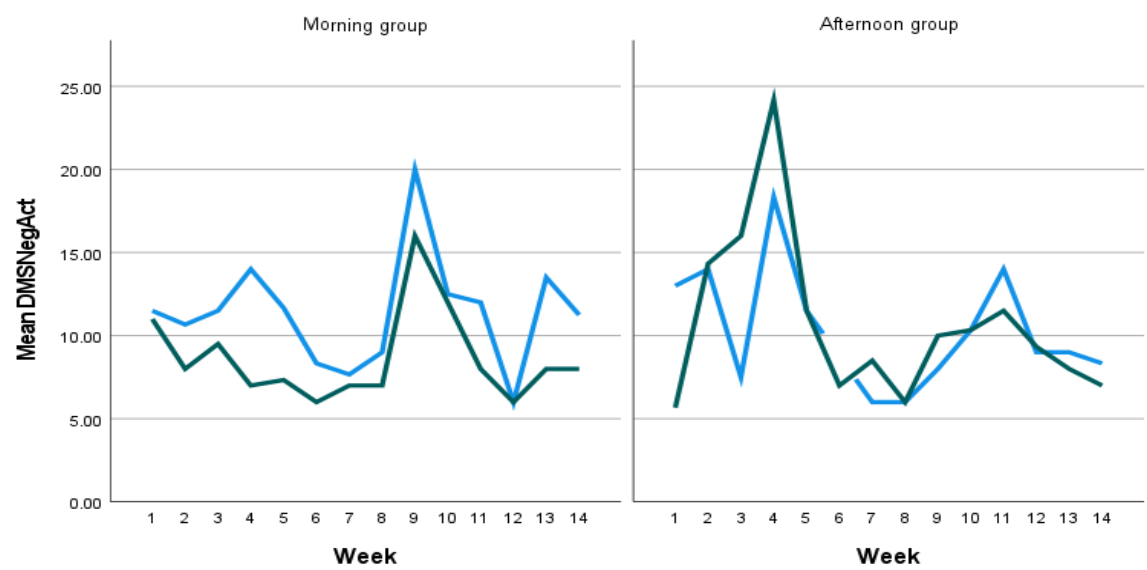
Positive Activation



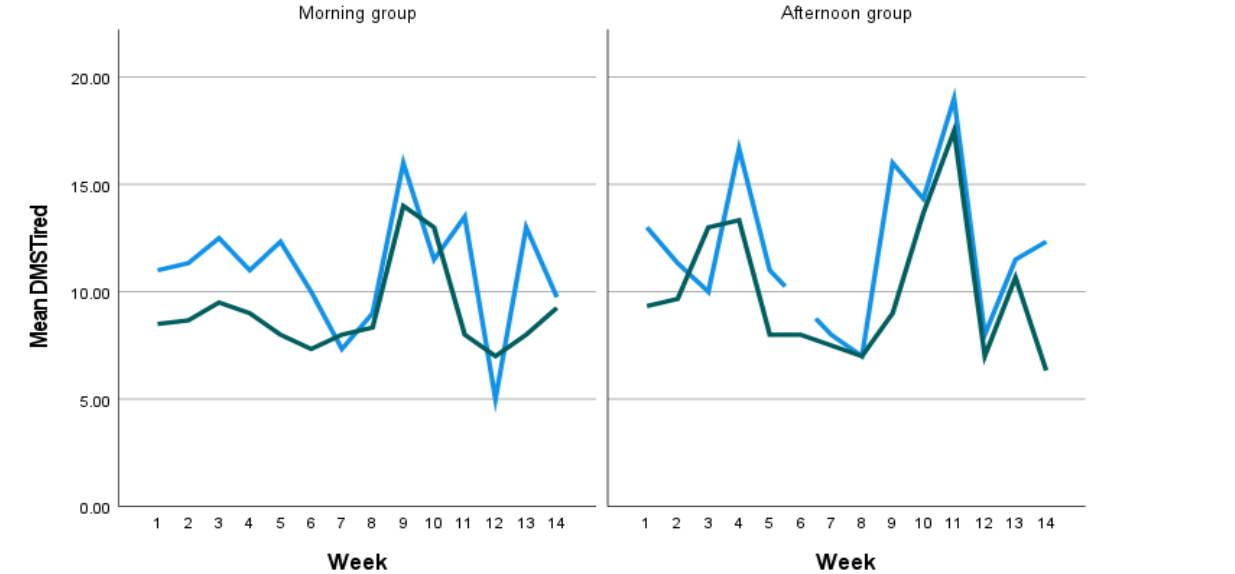
Relaxation

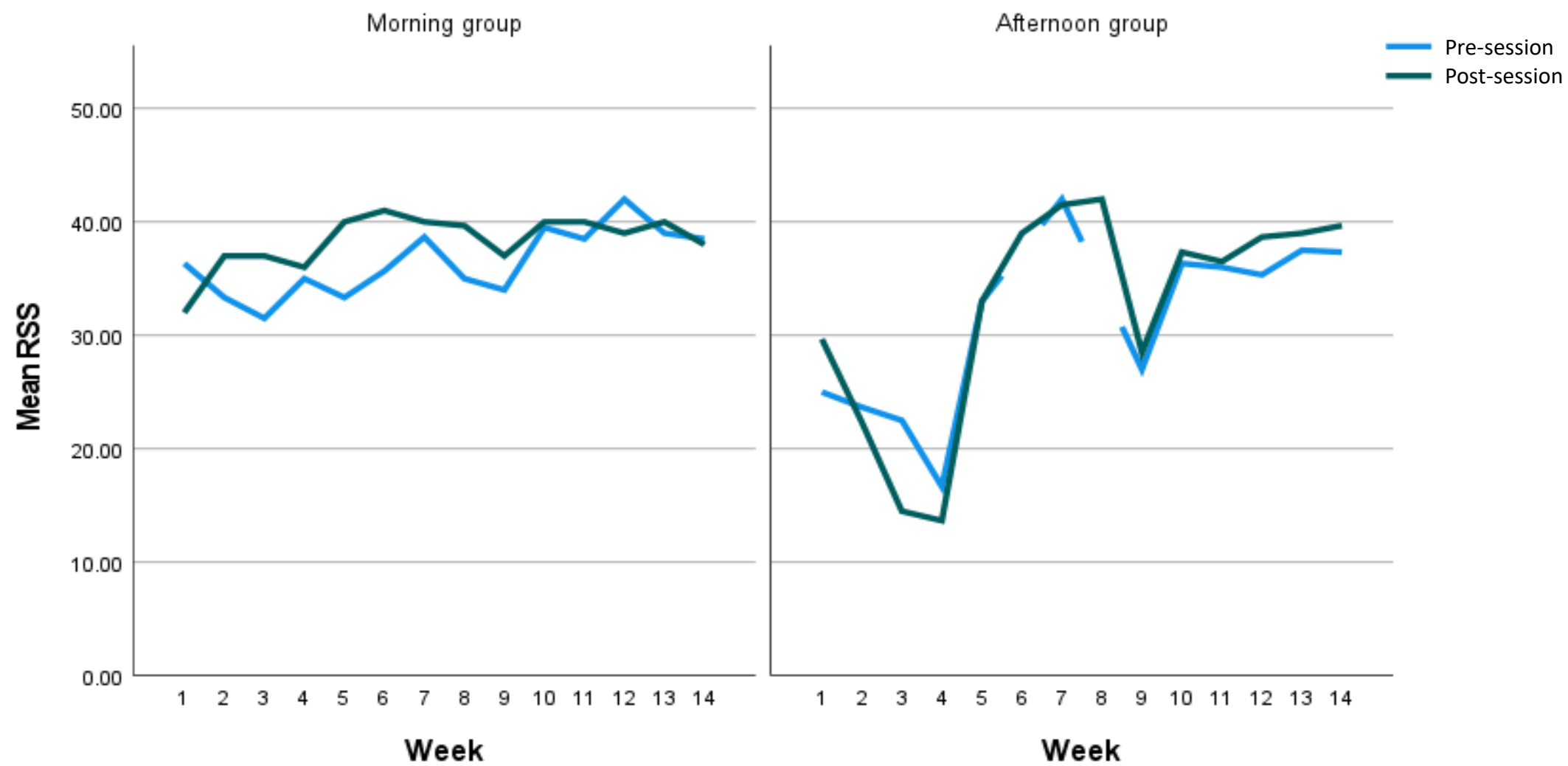


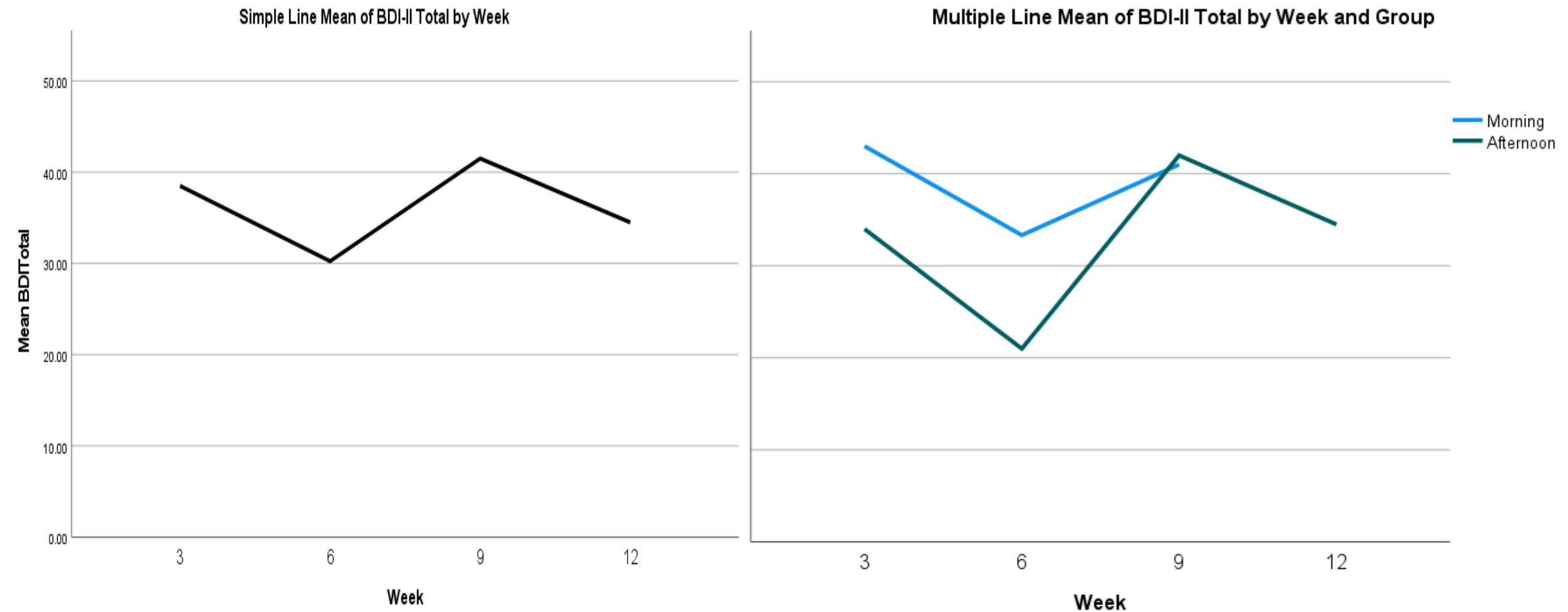
Negative Activation

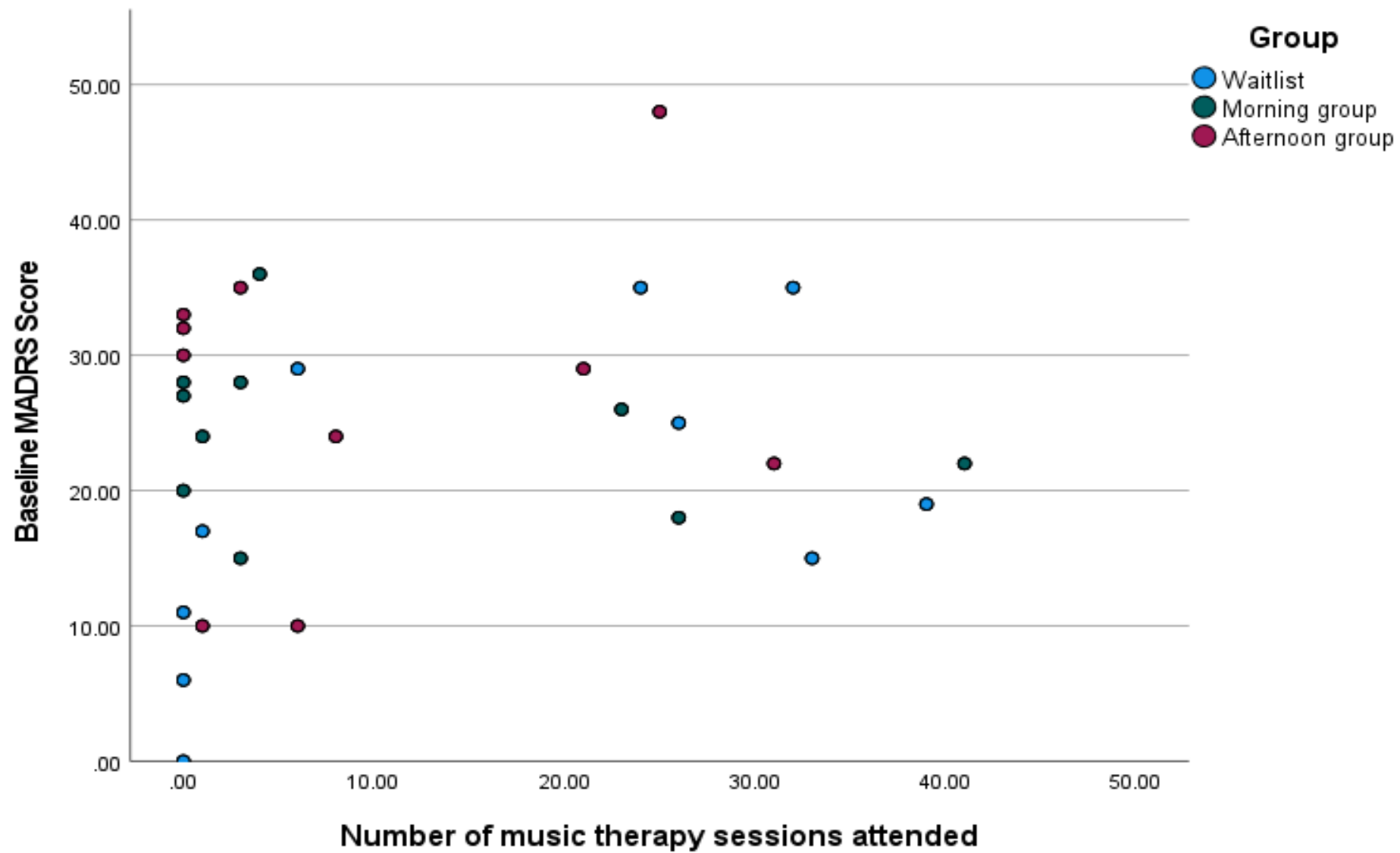


Tiredness











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Supplementary Material
AdditionalFile1.pdf





CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	2-3
Authors *	Contact details for the corresponding author	6-11
Trial design	Description of pilot trial design (eg, parallel, cluster)	27
Methods		
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	28-29
Interventions	Interventions intended for each group	30
Objective	Specific objectives of the pilot trial	25-26
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	31-36
Randomization	How participants were allocated to interventions	29-30
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	32
Results		
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	37-38
Recruitment	Trial status†	NA
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	40-41
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	37-48
Harms	Important adverse events or side effects	46
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	50-52
Trial registration	Registration number for pilot trial and name of trial register	53
Funding	Source of funding for pilot trial	54

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	P1 Line 2-3
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	P2 Line 24 to P2 Line 56
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	P4 Line 76-172
	2b	Specific objectives or research questions for pilot trial	P8 Line 178-190
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	P9 Line 192
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	P9 Line 199-206
Participants	4a	Eligibility criteria for participants	P9 Line 207-217
	4b	Settings and locations where the data were collected	P10 Line 219
	4c	How participants were identified and consented	P10 Line 219-234
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P10 Line 235-264
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	P12 Line 265-408
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	P9 Line 199
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	P55 Table 2
Sample size	7a	Rationale for numbers in the pilot trial	P18 Line 409
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not Applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P18 Line 423
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	P18 Line 423
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	P18 Line 425

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P18 Line 425-7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	P19 Line 428-36
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	P19 Line 437-57
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	P20 Line 460-77 Figure 1 Consort Diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	P21 Line 491-503
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P10 Line 230
	14b	Why the pilot trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	P56 Table 3
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Fig 1 CONSORT P56-63 Tables
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	P60 Table 5 P52 Table 6
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	P24-30 Figures 2-6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	P30 Line 693 P63Table 7
	19a	If relevant, other important unintended consequences	P30 Line 704
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	P35 Line 819
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	P35 Line 825-6
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	P31 Line 717-818
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	P35 Line 828-37

Other information			
Registration	23	Registration number for pilot trial and name of trial registry	P2 Line 53
Protocol	24	Where the pilot trial protocol can be accessed, if available	P9 Line 197-8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	P3 Line 54
	26	Ethical approval or approval by research review committee, confirmed with reference number	P9 Line 197 P38 Line 892

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
