

# Songs from home: addressing postnatal depression and loneliness through online songwriting

<b>Submission date</b> 13/09/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/06/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Feeling lonely increases the chance for mental illness among mothers. Factors that affect mothers' mental health require urgent attention because suicide is the leading cause of death among women with children under the age of 1 year. In the UK up to one in eight women experience postnatal depression (PND). This debilitating illness for mothers has implications for the fathers, babies, and mother-baby relationships. If women have low social support, this increases their chances of PND. Women with PND often describe feelings of isolation and loneliness.

While treatments are available for PND, alternatives are urgently needed; people often don't take their antidepressants as prescribed and long waiting lists mean a lack of access to psychological therapies. Treatments for loneliness are even more difficult to come by especially for women who – for financial, social, practical, or health barriers including COVID-19 – cannot attend in-person care. Promisingly, previous research conducted by the team showed that music interventions can support social connections and mother-baby bond, and reduce symptoms of PND.

The aim of this project is to develop and test an online music intervention based on songwriting, which has the goals of tackling loneliness and enhancing social connections through musical interactions in order to reduce symptoms of PND. Songwriting has been used in a range of clinical and online settings and fits well in an online context because it allows participants to join in a range of musical, creative, and social ways. Specifically, we address one overarching question: how can a collaborative online songwriting intervention which is accessible from home and led by an expert tackle loneliness and support social connections in order to reduce symptoms of PND?

### Who can participate?

Those who can participate are women who have a baby aged 9 months or younger, who have experienced loneliness and have reported symptoms of postnatal depression, and who are at least 18 years old.

What does the study involve?

Participants will take part in an online songwriting activity over 6 weeks. Half of the participants will take part right away (in September or November) and the other half will wait until January but answer questions about how they are feeling at the same time as those taking part in the earlier sessions. This way, responses to questions on loneliness, social connectedness, and postnatal depression can be compared between those taking part in the sessions and those not taking part to see if the songwriting activities make a difference in how people feel. Each week will include an online live session with the activity leader as well as an online workspace for the participants.

All participants will be asked to fill in online questionnaires about loneliness and depression 2 weeks before the first online workshop, after the final workshop, and once 4 weeks after the final workshop. In addition, they will be asked to complete a short questionnaire about loneliness after each of the six online workshops and 4 weeks after the final session. They will also be asked general information describing themselves.

After some of the sessions they will be asked some more open and closed questions about how they feel the activity is going, about loneliness and social connection, and about their thoughts about the songwriting activity in general. They will also be asked to let us know their ratings of ideas about the activity.

At the end of the 6 weeks there will be an online focus group discussion with other participants in each songwriting activity group to explore what they thought about the activity and how it can be improved, particularly in relation to issues of loneliness and PND.

Participants will be sent links to the online sessions, the online workspace, the questionnaires, and the focus group discussion, all of which can be completed from their own homes.

What are the possible benefits and risks of participating?

We hope that the research will support the development of a new song-writing activity tailor-made for new mothers experiencing loneliness and symptoms of PND. Participants will also have access to a free 6-week programme of songwriting classes for them and their baby.

We do not envisage any risks or lifestyle restrictions from taking part in this project, but the focus group discussion, completion of the questionnaires, and/or the songwriting sessions might lead to reflections about sensitive aspects of their experience of early motherhood. Information for sources for support will be provided in case any emotional distress is experienced.

Where is the study run from?

The study is being administered from the Royal College of Music, London, UK.

When is the study starting and how long is it expected to run for?

April 2021 to March 2022.

Who is funding the study?

It has been funded by the Loneliness & Social Isolation in Mental Health Research Network, which is funded by UK Research and Innovation (Grant reference: ES/S004440/1).

Who is the main contact?

Dr George Waddell, [george.waddell@rcm.ac.uk](mailto:george.waddell@rcm.ac.uk)

## Contact information

**Type(s)**

Public

**Contact name**

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**Type(s)**

Scientific

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

RCM P101

## Study information

**Scientific Title**

Songs from home: developing and testing an online songwriting intervention to tackle loneliness and enhance social connections in order to reduce symptoms of postnatal depression

### **Study objectives**

Current hypothesis as of 12/11/2021:

Among mothers who have a baby aged 9 months or younger and who have experience of loneliness and symptoms of postnatal depression, a 6-week online songwriting intervention:

1. Reduces loneliness
2. Reduces symptoms of postnatal depression
3. Enhances social connectedness

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Previous hypothesis:

Among mothers who have had a baby within nine months and who have experience of loneliness and symptoms of postnatal depression, a six-week online songwriting intervention:

1. Reduces loneliness
2. Reduces symptoms of postnatal depression
3. Enhances social connectedness

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 02/08/2021, Conservatoires UK Research Ethics Committee (Conservatoires UK, Woburn House, 20 Tavistock Square, London, WC1H 9HQ, UK; +44 (0)20 7419 4111; ethics@cassd.ac.uk), ref: CUK/SF/2020-21/5/2

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Internet/virtual

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Loneliness and postnatal depression among new mothers

### **Interventions**

Current intervention as of 12/11/2021:

This single-centre study comprises a randomised controlled trial in which new mothers with

experience of loneliness and symptoms of postnatal depression are randomly allocated to a non-intervention waitlist control group or to one of four 6-week, 1-hour-per-week group online songwriting interventions with data collected from all participants on loneliness, social connectedness, and symptoms of postnatal depression via online questionnaire.

The intervention group will take part in a 6-week online songwriting session led by one of two professional music workshop leaders. Each session will comprise 8-12 participants who will meet for 1 hour per week on Zoom from their homes and take part in structured, collaborative songwriting and music-making activities designed and led by the leader, including optional activities to be completed asynchronously between sessions and communicated via the online platform Trello. The waitlist control will engage in care as usual and take part in data collection measures at the same time points as the intervention group. Eligible mothers who have provided consent will be randomised between the control and treatment groups through an Excel random number generation procedure including stratification by severity of loneliness, severity of postnatal depression symptoms, and age of youngest baby. After the 6-week intervention, there is a 4-week follow-up.

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#### Previous intervention:

This single-centre study comprises a randomised controlled trial in which new mothers with experience of loneliness and symptoms of postnatal depression are randomly allocated to a non-intervention waitlist control group or to one of four six-week, 1-hour-per-week group online songwriting interventions with data collected from all participants on loneliness, social connectedness, and symptoms of postnatal depression via online questionnaire.

The intervention group will take part in a six-week online songwriting session led by one of two professional music workshop leaders. Each session will comprise 8-12 participants who will meet for one hour per week on Zoom from their homes and take part in structured, collaborative songwriting and music-making activities designed and led by the leader, including optional activities to be completed asynchronously between sessions and communicated via the online platform Trello. The waitlist control will engage in care as usual and take part in data collection measures at the same time points as the intervention group. Eligible mothers who have provided consent will be randomised between the control and treatment groups through an Excel random number generation procedure including stratification by severity of loneliness, severity of postnatal depression symptoms, and age of youngest baby. After the 6 week intervention, there is a two week follow up.

#### **Intervention Type**

Behavioural

#### **Primary outcome measure**

Current primary outcome measure as of 12/11/2021:

Loneliness is measured using the UCLA 3-Item Loneliness Scale (UCLA-3; Masi et al., 2010) via online questionnaire at baseline 2 weeks in advance, immediately following each of the 6 online sessions (or equivalent time for the control), and at follow-up 4 weeks after the end of the intervention.

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#### Previous primary outcome measure:

Loneliness is measured using the UCLA 3-Item Loneliness Scale (UCLA-3; Masi et al., 2010) via online questionnaire at baseline two weeks in advance, immediately following each of the 6

online sessions (or equivalent time for the control), and at follow-up two weeks after the end of the intervention.

### **Secondary outcome measures**

Current secondary outcome measures as of 12/11/2021:

1. Postnatal depression is measured using the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987) via online questionnaire at baseline 2 weeks in advance, immediately following the final online session, and at follow-up 4 weeks after the end of the intervention.
2. Social connectedness is measured using the Social Connectedness Revised 15-item Scale (Lee et al., 2008) via online questionnaire at baseline 2 weeks in advance, immediately following the final online session, and at follow-up 4 weeks after the end of the intervention.

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Previous secondary outcome measures:

1. Postnatal depression is measured using the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987) via online questionnaire at baseline two weeks in advance, immediately following the final online session, and at follow-up two weeks after the end of the intervention.
2. Social connectedness is measured using the Social Connectedness Revised 15-item Scale (Lee et al., 2008) via online questionnaire at baseline two weeks in advance, immediately following the final online session, and at follow-up two weeks after the end of the intervention.

### **Overall study start date**

01/04/2021

### **Completion date**

31/03/2022

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 12/11/2021:

1. Aged 18+
2. Based in the UK
3. A woman who has a baby aged 9 months or younger
4. Have experienced loneliness (as per score of 4+ on UCLA-3)
5. Have symptoms of postnatal depression (as per score of 10+ on EPDS)
6. Have capacity to consent

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Previous inclusion criteria:

1. Aged 18+
2. Based in the UK
3. A woman who has had a baby within previous 9 months
4. Have experienced loneliness (as per score of 4+ on UCLA-3)
5. Have symptoms of postnatal depression (as per score of 10+ on EPDS)
6. Have capacity to consent

### **Participant type(s)**

Other

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

68

**Total final enrolment**

94

**Key exclusion criteria**

None beyond not meeting the inclusion criteria.

**Date of first enrolment**

17/09/2021

**Date of final enrolment**

31/10/2021

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal College of Music**

Prince Consort Road

London

United Kingdom

SW7 2BS

## **Sponsor information**

**Organisation**

Royal College of Music

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**Sponsor type**

University/education

**Website**

<http://www.rcm.ac.uk/>

**ROR**

<https://ror.org/04kwn3124>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

UK Research and Innovation (Loneliness & Social Isolation in Mental Health Research Network)

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Study results will be published in high-impact, peer-reviewed journals.

**Intention to publish date**

31/03/2023

**Individual participant data (IPD) sharing plan**



Current IPD sharing statement as of 12/11/2021:  
Anonymised data will be shared via a publicly available repository.

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Previous IPD sharing statement:

The datasets generated during and/or analysed during the current study are not expected to be made available as this intervention represents a pilot study with a relatively small sample and limited quantitative variables (i.e. will not be conducive to further analysis), and securing explicit consent to share these data in such a way has not been included in the consenting process approved by our ethics committee.

### IPD sharing plan summary

Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			15/09/2021	No	Yes
<a href="#">Results article</a>		02/06/2023	05/06/2023	Yes	No
<a href="#">Dataset</a>		24/05/2023	28/06/2023	No	No