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Mindfulness for trauma

Submission date	Recruitment status	[X] Prospectively registered
10/01/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/01/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Women who have experienced domestic violence and abuse (DVA) often develop post-traumatic stress disorder (PTSD) which includes reliving the traumatic events through nightmares and disturbing memories, feeling isolated, irritated and guilty, having difficulties with concentration and functioning. Children whose mothers have PTSD are at risk of developing mental health problems. Unlike a one-off traumatic event, repeated DVA results in PTSD that is harder to treat. Standard treatment for PTSD is a past-focused talking therapy which teaches how to change negative thoughts and feelings into more positive ones through 'reliving' traumatic memories. Many survivors of DVA drop out of the standard treatment because they find such an approach too upsetting or do not feel better. In contrast, mindfulness is a present focused talking therapy which teaches how to respond to one-self with acceptance and self-compassion. It is known that mindfulness works well for depression. In collaboration with DVA survivors and mental health professionals, the researchers have adapted a standard mindfulness course for depression to fit the special treatment preferences and needs of DVA survivors with PTSD. Now they plan to test the trauma-specific mindfulness course for PTSD in a small study. This will help them to design a bigger study which will answer the question about the effectiveness and value for money of the adapted mindfulness course.

Who can participate?
Women service users at collaborating DVA agency, aged 18 and over, with clinically important symptoms of PTSD

What does the study involve?
54 service users with PTSD are randomly allocated into two groups. Two- thirds (updated 22/10 /2019, previously: Half) of the women attend eight mindfulness group sessions, while the other third (updated 22/10/2019, previously: half) receive the standard talking therapy on the NHS. The two groups are compared with respect to mental health status of women and their children before the allocation and six months later. All patients are also interviewed about their treatment experiences.

What are the possible benefits and risks of participating?
Women will have a 75% chance of getting a new talking therapy. However, it is not yet known whether it is helpful. By taking part, women will be having a say in whether the new mindfulness course is acceptable and should be tested in a bigger study. Taking part in the study means that

woman will have additional contacts with the study researcher over a period of six months. This may increase the risk of other people including perpetrator of DVA finding out about woman's participation in the study which can potentially lead to escalation of abuse. However, the researchers will always do their best to contact participants in a safe way. For example, they will only phone the woman at a time when she tells us it is safe to do so. They will also arrange safe places to meet with or be contacted by the researcher and to store study documentation. Participant's safety will always be their priority.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
June 2018 to September 2020

Who is funding the study?
The NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol (UK)

Who is the main contact?
Dr Natalia Lewis
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38155

Study information

Scientific Title
A feasibility trial of a trauma-informed mindfulness intervention for survivors of domestic violence and abuse with post-traumatic stress disorder

Acronym
coMforT

Study objectives
Current study hypothesis as of 06/09/2021:

It is feasible to conduct a full-size trial of a trauma-specific mindfulness intervention for the treatment of post-traumatic stress disorder in women survivors of domestic violence and abuse?

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Previous study hypothesis:

A trauma-informed mindfulness intervention co-produced with stakeholders is acceptable to women survivors of domestic violence and abuse and feasible to deliver.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Health Sciences Research Ethics Committee, University of Bristol, 1 Cathedral Square, Bristol, BS1 5DD, Tel: +44 (0)117 42 84051, Email: Liam.McKervey@bristol.ac.uk, 05/02/2018, ref: 2851 & 2018 - 2038 (Id nr.: 72206)

Study design
Randomised; Both; Design type: Treatment, Complementary Therapy, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Post-traumatic stress disorder

Interventions
Current interventions as of 06/09/2021:

The trialists will recruit 54 women with PTSD from DVA agency and randomly allocate them into two arms. Two thirds of the women will attend eight trauma-specific mindfulness group sessions, while the other third will receive the standard past-focused talking therapy. The two groups will be compared with respect to mental health status of women before the allocation and six months later. The trialists will also interview all women about their treatment and study experiences. If they find that the trauma-specific mindfulness course is acceptable and that the study plan could work, they will design a full size trial and apply for funding.

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Previous interventions as of 22/10/2019:

The trialists will recruit 54 women with PTSD from DVA agency and randomly allocate them into two arms. Two thirds of the women will attend eight mindfulness group sessions, while the other third will receive the standard past-focused talking therapy. The two groups will be compared with respect to mental health status of women before the allocation and six months later. The trialists will also interview all women about their treatment and study experiences. If they find that the mindfulness course is acceptable and that the study plan could work, they will design a full size trial and apply for funding.

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Previous interventions:

The trialists will recruit 54 women with PTSD from DVA agency and randomly allocate them into two arms. Half of the women will attend eight mindfulness group sessions, while the other half will receive the standard past-focused talking therapy. The two groups will be compared with respect to mental health status of women before the allocation and six months later. The trialists will also interview all women about their treatment and study experiences. If they find that the mindfulness course is acceptable and that the study plan could work, they will design a full size trial and apply for funding.

Intervention Type
Behavioural

Primary outcome measure
Primary feasibility outcomes:
Recruitment/randomisation rate is measured as a proportion of participants recruited /randomised into two arms; the denominator will be the number of participants eligible for recruitment/randomisation by the end of the randomisation period.

Secondary outcome measures

Current secondary outcome measures as of 22/10/2019:
Secondary feasibility outcomes:
1. Intervention uptake is measured as a proportion of participants who took up the intervention and usual care; the denominator will be the number of participants randomised in the arm, respectively, at 6 month post-randomisation
2. Intervention retention is measured as a proportion of participants in the intervention arm who received the “minimum dose” of the intervention, four sessions of mindfulness intervention, at 6 months post-randomisation
3. Follow-up rate is measured as a proportion of participants followed up at six months post-randomisation out of those enrolled in the trial. The proportion who have been lost to follow-up will also be calculated by the trial arms, at 6 months post-randomisation
4. Participant experiences of the study is evaluated through qualitative interviews at completion of the intervention

Previous secondary outcome measures:
Secondary feasibility outcomes:
1. Intervention uptake is measured as a proportion of participants who took up the intervention and usual care; the denominator will be the number of participants randomised in the arm, respectively, at 6 month post-randomisation
2. Intervention retention is measured as a proportion of participants in the intervention arm who received the “minimum dose” of the intervention, four sessions of mindfulness intervention, at 6 months post-randomisation
3. Follow-up rate is measured as a proportion of participants followed up at six months post-randomisation out of those enrolled in the trial. The proportion who have been lost to follow-up will also be calculated by the trial arms, at 6 months post-randomisation
4. Participant experience is evaluated through qualitative interviews at 6 months post-randomisation

Overall study start date
01/06/2018

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Target population: service users from third sector DVA agency:
1. Female
2. Referred or self-referred to collaborating third sector organisation for DVA advocacy
3. No physical or sexual victimization in the prior two months
4. Meeting the DSM-5 diagnostic criteria for PTSD, as measured by the clinician administered PTSD scale

The trialists will recruit women with and without children to explore the feasibility of measuring mother-reported outcomes for children. They won't identify or contact children.

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
Planned Sample Size: 54; UK Sample Size: 54

Total final enrolment
20

Key exclusion criteria
Exclusion criteria for women service users are derived from exclusion criteria for a standard MBCT course:
1. Unable to provide written informed consent
2. Inability to read or write in English (because interventions will be delivered in English)
3. Current drug or alcohol dependency
4. Organic brain damage
5. Current or past psychosis
6. Persistent self-harm or suicide risk requiring management
7. Already receiving psychological therapy -physical or sexual DVA within past 2 months

Date of first enrolment
14/01/2019

Date of final enrolment
07/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Next Link
5 Queen Square
Bristol
United Kingdom
BS1 4JQ

Study participating centre
Blackberry Hill Hospital
Avon & Wiltshire Mental Health Partnership NHS Trust

Bristol
United Kingdom
BS16 2EW

Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Bristol Biomedical Research Centre; Grant Codes: BRC-1215-20011

Results and Publications

Publication and dissemination plan
1. Protocol paper: 30/03/2019
2. Main paper: 30/05/2022
3. At least three conference presentations. (added 06/09/2021)

Intention to publish date
30/05/2022

Individual participant data (IPD) sharing plan

Current IPD sharing plan:
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. After the study has concluded, the trialists will deposit the anonymised data in the University of Bristol Research Data Repository data.bris (https://doi.org/10.5523/bris.j4jsx8boace42hg58jcvyinlo) where it will be made available to other healthcare researchers. All requests for sharing will be assessed by a data access committee to check they are authentic research requests.

The type of data stored - Qualitative research data from phase 1 includes a table with socio-demographic characteristics of interview participants (professionals and women with a history of domestic abuse), anonymized interview transcripts, and study documentation (participant information sheets, consent forms, case report forms). Research data from phase 2 includes participant information sheets, consent forms, case report forms, a quantitative trial dataset with raw data and a data dictionary and a qualitative dataset of interview transcripts.
The process for requesting access - Controlled access. Access is limited to bona fide researchers only, and governed by an institution-level Data Access Committee. Guidance on accessing research data: http://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/
Dates of availability - April 2018-February 2020.
Whether consent from participants was required and obtained - Participants provided written informed consent.
Comments on data anonymization - The produced data have a small risk of re-identification, after the use of pseudonyms and removal of direct identifiers.
Any ethical or legal restrictions - Non-Commercial Government Licence for public sector information (https://www.nationalarchives.gov.uk/doc/non-commercial-government-licence/version/2/)

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. After the study has concluded, the trialists will deposit the anonymised data in the University of Bristol Data Repository where it will be made available to other healthcare researchers. All requests for sharing will be assessed by a data access committee to check they are authentic research requests.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/02/2020	13/03/2020	Yes	No
Results article		03/07/2023	04/07/2023	Yes	No