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CoMforT study: Intervention refinement and feasibility trial of a trauma-informed mindfulness intervention for survivors of domestic violence and abuse with posttraumatic stress disorder

Background

• Women who have experienced domestic violence and abuse (DVA) often develop post-traumatic stress disorder (PTSD).
• In collaboration with service users, we have started adapting a standard mindfulness course for depression (Mindfulness Based Cognitive Therapy (MBCT)) to fit the special treatment preferences and needs of DVA survivors.

Aim

I. To produce a trauma-informed MBCT intervention (TI-MBCT) that it is acceptable to key stakeholders and feasible to deliver.
II. To assess the feasibility of proceeding to a definitive trial of a TI-MBCT intervention vs usual care for the treatment of PTSD in women with experience of DVA.

Study design

Phase I. Intervention refinement

2014 pre-pilot work -- TI-MBCT prototype 1
(Thesis 'How can an adapted MBCT course meet the specific vulnerabilities of women survivors of DVA')

Summary of adaptations in TI-MBCT prototype 1

2-round consensus exercise with mindfulness experts by experience (n=20):
1. Online questionnaire
2. Meeting

Protocol and materials for TI-MBCT prototype 2

Updated 2014 literature review on mindfulness-based treatments for PTSD and DVA populations

Statement on areas of uncertainty

Primary qualitative study:
- Survivors' feedback on TI-MBCT prototype 1 from 2014 pre-pilot work
- Interviews with professionals and service users (n=20)

Summary of literature review and qualitative findings

Phase II. Feasibility trial

Screening

Excluded (n=)
- Reasons (n=)

Enrolment

Assessed for eligibility (n=)

Randomised (n=)

Allocation

TI-MBCT prototype 2 group (n=)
- Received intervention (n=)
- Did not receive intervention with reasons (n=)

TI-MBCT prototype 3 group (n=)
- Received intervention (n=)
- Did not receive intervention with reasons (n=)

6-m follow-up

Assessment and process evaluation

Assessed for each objective (n=)

IAPT usual care for PTSD (n=)
- Received intervention (n=)
- Did not receive intervention with reasons (n=x)

Process evaluation and further refinement

Study timeline

Oct 2017
Start

April-Nov 2018
Intervention refinement

March 2018
Ethics & HRA approvals

Dec 2018-June 2020
Feasibility trial

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