ISRCTN54036115 https://doi.org/10.1186/ISRCTN54036115

Multicentre Intervention Designed for Self-Harm using Interpersonal Problem Solving: a feasibility study

Submission date
07/10/2011

Recruitment status
No longer recruiting

Registration date
13/01/2012

Overall study status
Completed

Last Edited
27/08/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People who attend NHS hospitals because of self-harm (mainly overdose or self-cutting) receive a variable standard of care. Often, they are not assessed for their psychological needs, and psychological therapy is offered and taken up haphazardly. This is a key health concern because self-harm is very common (around 150,000 people attend hospitals in England each year) and it is the major risk factor that points towards later suicide. Many people repeat self-harm but we dont know how to reduce this repetition, although brief problem-solving therapies are considered the most promising option.

Who can participate?
After hospital treatment for their physical state and assessment of social and psychological needs, we propose that adults who have self-harmed are invited to join the research.

What does the study involve?
If they consent to take part we will randomly allocate the arrangements for their aftercare. In the two months following the self-harm, half will receive treatment-as-usual; the others will also be offered four to six one-hour sessions of problem-solving therapy from a trained person (usually a mental health nurse or social worker). The therapy offers a structured approach to identifying current problems and is a guide towards ways of solving these and future problems. Over the next year we will find out whether participants have repeated self-harm and if their general health and psychological well-being has improved, comparing these outcomes among those who did and did not receive the problem-solving therapy.

We plan to carry out our research in 12-15 hospitals around England but in the present project we will be finding out only whether it is feasible to run a large trial: getting the therapy standardised and therapists trained, finding out how many people we can recruit, checking that we can deliver the therapy to them over four to six sessions, and that we can collect information about their health and any further self-harm. In this way we can design an achievable trial of problem-solving therapy for self-harm.

What are the possible benefits and risks of participating?
The main benefits of the study are that we will find out more about how to help people who have self-harmed, and the study results will inform the development of a definitive study which will have the aim of recommending whether or not problem-solving therapy is an effective approach for people following self-harm. We do not expect there to be any risks in taking part.

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

When is the study starting and how long is it expected to run for?
Set up started in September 2011. Recruitment of participants was intended from June to November 2012, with a six-month follow-up phase lasting until May 2013. However, recruitment ran from October 2012 to October 2013. Follow-up will be complete by end April 2014, and analysis by July 2014.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme.

Who is the main contact?
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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
PB-PG-0610-22267

Study information

Scientific Title
MIDSHIPS: Multicentre Intervention Designed for Self-Harm using Interpersonal Problem Solving: a feasibility study

Acronym
MIDSHIPS

Study objectives
The aim of the study is to determine the practicability of undertaking a large randomised controlled trial of interpersonal problem-solving therapy plus treatment as usual (TAU), compared with TAU only, for adults who attend hospital due to self harm.

Updated 20/08/2013: recruitment will be completed by 30/10/2013, follow-up by the end of April 2014 and analysis by July 2014. The overall trial end date was changed from 01/06/2013 to 01/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire and the Humber - Leeds West, 04/04/2012, ref: 12/YH/0022

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Self-harm in adults

Interventions

Interpersonal Problem Solving Therapy (PST) will be delivered by therapists who have received trial-specific training in the intervention. Participants randomised to problem-solving therapy will receive 4 to 6 one-hour weekly sessions delivered by the trial therapists. Participants randomised to receive PST will also receive TAU.

TAU following self harm varies and may involve such diverse pathways as: referral to a multi-disciplinary team for psychiatric or psychological intervention; referral to a mental health crisis team and recommendation for engagement with other health and non-health services such as alcohol and drug treatment centres. In many cases no aftercare is offered and the only action to follow the discharge from hospital is the sending of a general practitioner (GP) letter summarising the episode. We will record TAU for all participants who consent to follow up in the control and intervention arms of the trial.

Patients in both arms of the trial will be followed up for 6 months post-randomisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
As this is a feasibility study, the outcomes relate to the feasibility of recruitment, therapeutic delivery, retention in therapy and outcome data collection. These are as follows:

1. Establishing the problem solving intervention:
1.1. Agreed process for recruiting therapists
1.2. Agreed training manual and procedure for training therapists
1.3. Agreed method for assessing therapist competence
1.4. Agreed procedure for ongoing supervision of therapists
2. Recruitment methods, uptake and follow-up:
2.1. Agreed method for screening for eligibility
2.2. Proportion screened for eligibility out of number seen in the Emergency Department (ED)
2.3. Number of study cards given out and proportion completed
2.4. Proportion eligible out of those followed-up by the Researcher
2.5. Proportion that consent to the study out of those found eligible
2.6. Proportion randomised out of those that consent
2.7. Reasons for non-participation
2.8. Proportion completing the study out of those randomised, number of withdrawals from the study, reasons for withdrawal
3. Therapeutic delivery:
3.1. Proportion of participants randomised to the intervention arm successfully completing the required number of therapy sessions as agreed with the study therapist
3.2. Agreed method for measuring participant and therapist adherence to the problem solving therapy including, number of problem solving therapy sessions undertaken, number of tasks written in the participants workbooks , number of early drop-outs from treatment, reasons for early drop outs
3.3. Map the range of treatment-as-usual pathways across treatment groups
4. Follow-up data collection:
4.1. Proportion of participants with available repetition of self-harm data, accessed via hospital records compared to NHS data sources, at 6 months post-randomisation

4.2. Proportion of participants with self-reported outcome data, proportion obtained through postal administration and where not available telephone interviews at 3 and 6 months post-randomisation
4.3. Missing item level data on self-reported questionnaires
5. Statistical outcomes:
5.1. Variability of the self-reported outcomes at 3 and 6 months post-randomisation
5.2. Repetition of self harm leading to hospital attendance event rate in control arm at 6 months post-randomisation
5.3. Clustering effect (ICC) relating to therapists in other relevant studies
5.4. Difference in self-harm rates leading to hospital attendance per treatment group at 6 months post-randomisation
5.5. Difference in self-reported outcomes per treatment group at 3 and 6 months post-randomisation
5.6. 95% confidence intervals for the difference in outcomes between the control and intervention groups

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Attended the emergency department or admitted to general hospital as a consequence of self-harm within the last six weeks
3. Not already participating in the MIDSHIPS trial
4. Where the presenting episode is due to alcohol or recreational drugs, there has been an explicit statement that he / she was intending self-harm by use of alcohol/recreational drugs

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
62

Key exclusion criteria
1. Involved in another research project (involving an active intervention, which would conflict with MIDSHIPS)
2. Does not live in the LPFT catchment area
3. Refuses to provide fully informed written consent
4. Lacks capacity to comply with trial requirements
5. Insufficient proficiency in English to contribute to the data collection required for the research
6. Known risk of violence
7. Researcher unable to contact participant within eight weeks following self-harm event

Date of first enrolment
01/10/2012

Date of final enrolment
30/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Institute of Health Sciences
Leeds
United Kingdom
LS2 9LJ

Sponsor information

Organisation
Leeds Partnerships NHS Foundation Trust (UK)

Sponsor details
c/o Sinead Audsley
Leeds Partnerships NHS Foundation Trust
Research & Development Department
St Mary's House
Leeds

England
United Kingdom
LS7 3LA

Sponsor type
Hospital/treatment centre

Website
http://www.leedspft.nhs.uk/

ROR
https://ror.org/00n635c12

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Program (ref: PB-PG-0610-22267)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2018 results in https://medhealth.leeds.ac.uk/info/414/mental_health/1676/midships .

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/05/2014		Yes	No
Results article	results	19/08/2020	27/08/2020	Yes	No