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Trialling an optimised social groups intervention in services to enhance social connectedness and mental health in young people

Submission date
08/04/2022

Recruitment status
No longer recruiting

Registration date
11/04/2022

Overall study status
Completed

Last Edited
16/08/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims:
We are testing an intervention called 'Groups 4 Health'. The intervention was designed by a team in Australia to support people to identify and develop connections with new people or social groups. Past research has found that the intervention can help people with their feelings of loneliness, their connections with other people, and their well-being. To understand if the intervention might be helpful for young people in the United Kingdom, it first needs to go through a small pilot research study.

This project will help us to learn:
1) What the experience of the intervention is like for young people currently experiencing mental health difficulties
2) What the intervention is like to deliver for members of staff delivering the intervention
3) Do our plans for this research study work?
4) This information will help us to learn whether we can run a larger study to test whether the intervention is helpful.

Who can participate?
This study is suitable for young people (aged 16-25 years) who are currently experiencing difficulties with their mental health and well-being.

What does the study involve?
Participants will meet with a researcher at three time points (baseline, 10 week and 14 week post-randomisation). Participants will also be randomised to receive the intervention alongside their usual treatment, or receive their usual treatment only. Participants randomised to receive the intervention, will receive the intervention by a trained practitioner from the community, health and/or youth mental health service they access.

What are the possible benefits and risks of participating?
This study will involve answering questions about mental health and social wellbeing. Some people in similar research studies have told us they find it interesting or helpful to answer such questions. However, some people can find it difficult or distressing. Some of the questions asked are of a potentially sensitive nature. For example, a small number of questions ask about low mood and suicidal thoughts.

We hope that those receiving the Groups 4 Health intervention will find it helpful. However, this cannot be guaranteed. By taking part in this study, participants will help us to learn about how helpful the intervention might be, and whether we should try and test this in a bigger project. Participants will also be helping us to learn how we can optimise the intervention.

Where is the study run from?
The University of Sussex

When is the study starting and how long is it expected to run for?
From April 2022 to September 2023

Who is funding the study?
The Applied Research Collaboration in Kent, Surrey and Sussex

Who is the main contact?
Claire Vella
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
309287

Central Portfolio Management System (CPMS)
51865

Study information

Scientific Title
Trialling an Optimised social Groups intervention in services to Enhance social connecTedness and mental Health in vulnERable young people (TOGETHER): a feasibility study

Acronym
TOGETHER

Study objectives
1. Is it feasible to conduct a randomised controlled trial for the Groups 4 Health (G4H) intervention when delivered to young service-users accessing community, health and/or youth mental health services?

2. Is the G4H intervention feasible to deliver to young service-users involved in community, health and/or youth mental health services?
3. Is the G4H intervention safe and acceptable according to both the young service-users receiving the intervention, and the practitioners delivering the intervention?
4. What changes are indicated to improve the safety, acceptability, accessibility and feasibility of the intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/03/2022, Berkshire Research Ethics Committee (Temple Quay House, BS1 6PN; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 22/SC/0040

Study design
Multicenter interventional blinded feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Social connectedness and mental health in vulnerable young people

Interventions
5 session adapted Groups 4 Health (G4H) intervention, delivered by trained practitioners within an ~8 week time frame. Participants are randomised, stratified by site, to receive the intervention alongside treatment as usual, or receive treatment as usual only.

Randomisation will be completed by a co-investigator statistician, who will not be involved in the research and intervention delivery, nor data analysis, using the Sealed Envelope online service. One of the trial study coordinators will be unblind during the trial. All other study team members will be blind to the randomisation procedure and allocation sequence.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility will be measured using the following:
1. Number of potential service-user participants referred each month throughout the recruitment period
2. Number of intervention providers from services involved in the trial aspect of the study who consent to take part each month throughout the recruitment period
3. Number and proportion of referred potential service-user participants who consent to take part in the study each month throughout the recruitment period
4. Number and proportion of referred potential service-user participants found to be eligible each month throughout the recruitment period
5. Number and proportion of consenting eligible participants who are retained in the study post-randomisation at 10 weeks and 14 weeks

6. Number and proportion of survey measures completed by each participant at baseline, 10 weeks, and 14 weeks
7. Number and proportion of consenting eligible service-user participants who take part in all five G4H sessions throughout the 8 week intervention period
8. Number and proportion of intervention adherence components completed for each session and across the whole G4H intervention throughout the 8 week intervention period
9. Number and nature of adverse events experienced by study participants each month throughout the 8 week intervention period
10. Number and proportion of breaks in blinding each month throughout the 14 week study period

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Aged 16 – 25 years old
2. Accessing a community, health and/or youth mental health service involved in the study
3. Experiencing current mental health difficulties (operationalised by a rating of ≤60 on the Global Assessment Scale (GAS))
4. Able to read, write and speak in English, or are non-English speaking but have access to an interpreter, to the degree they can give informed consent and are able to fully understand and participate in both the assessment questions and intervention content

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
16 years

Upper age limit
25 years

Sex
Not Specified

Key exclusion criteria
1. At immediate and serious risk to self or others (assessed at the point of referral/eligibility review)
2. Currently participating, or be confirmed to participate in another interventional research

study in which they are receiving an intervention that targets social isolation or utilises psychological therapy
3. Expected to be discharged, or be known to be unable to seek support from the referring service, in the 16 weeks following a referral to the trial being made (14 week research involvement + 2 weeks allowing for any missed/rearranged meetings)

Date of first enrolment
18/04/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Claire Vella (c.vella@sussex.ac.uk). The type of data available will be anonymised quantitative and qualitative data, regarding intervention and research process feasibility, and trial outcome data. Participant consent was provided for data sharing for the purposes of research. There are no known other ethical nor legal restrictions. Data will become available from October 2023 for an indefinite period.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/08/2023	16/08/2023	Yes	No
HRA research summary			28/06/2023	No	No