ISRCTN17197043 https://doi.org/10.1186/ISRCTN17197043

A feasibility randomised controlled trial of a peer-delivered disclosure programme (Let's Talk) for internalised stigma experienced by people with psychosis

Submission date
02/08/2021

Recruitment status
No longer recruiting

Registration date
11/08/2021

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

Psychosis is when people lose some contact with reality, which might involve seeing or hearing things that other people cannot see or hear (hallucinations) and believing things that are not actually true (delusions). Some people who experience psychosis say that at times they have faced negative attitudes from others about psychosis (this is called stigma), or that they have been treated unfairly because of their experiences (this is called discrimination). This may lead some people to think or feel negatively about themselves (this is called internalised stigma). Weighing up decisions about 'disclosing' or talking about a mental health difficulty to others can be difficult because of concerns about stigma. People may be unsure what to say to a friend or loved one about their mental health, feel they need to keep things a secret or be worried about other people finding out about how things have been with their mental health. One approach to helping people if they are concerned about this is the 'Let's Talk' programme that aims to help people think about the upsides and downsides of talking about mental health in the daily settings of life, learn ways to talk about their mental health and support them to make the best decisions. Let's Talk has been delivered in a group setting but not all people like going to groups or cannot go to groups for practical reasons. So, the aim of this study is to find out if Let's Talk can be helpful when done one-to-one with a peer support worker's support. A Peer Support Worker (PSW) is a person who has also experienced similar mental health difficulties and can offer connection and understanding. Findings from this study will help to show whether the researchers should do a larger study and how best it should be done.

Who can participate?

People who have experience of psychosis (e.g. either have met entry criteria for an Early Intervention in Psychosis Service and/or have received a schizophrenia spectrum diagnosis), who are aged 16 years or over and who have expressed that mental health stigma has had some impact on both their wellbeing and on them talking to others about their mental health.

What does the study involve?
Participants will be randomly allocated by a computer system (50:50 chance) to one of two groups to receive either standard care (the usual care received by the participant's care team), or standard care plus the Let's Talk programme (e.g. the care participants would usually receive via their care team plus up to eight sessions of the Let's Talk programme over a 10-week period). The goal of the Let's Talk programme is to support people who experience psychosis with thinking through the upsides and downsides of talking about their experiences of psychosis experiences in the daily settings of their life (friendships, family, etc). With a peer support worker (PSW) the participant can explore ways to talk about their experiences of psychosis that have worked for others. The Let's Talk programme aims to empower people with psychosis to make informed decisions regarding mental health disclosure based on their own personal circumstances. Those allocated to receive the Let's Talk programme will be provided with a workbook containing information to support them in making these decisions and their allocated Peer Support Worker will work with the participant as they move through the sections in the workbook. All participants will be offered a research assessment at the start of the study and at 2.5-months and 6-months follow-up.

What are the possible benefits and risks of participating?
For those allocated to receive the Let's Talk programme it is possible, but not guaranteed, that the intervention may be helpful in several ways. It may help reduce the impact that stigma has by supporting them to think through the upsides and downsides of talking about mental health in the daily settings of life. It may help participants to learn ways to talk about themselves that have worked for others and support them to make the best decision for themselves. Meeting with a peer will allow them the opportunity to talk to someone who has experienced similar mental health difficulties and can offer understanding and support. It is possible that they will help reduce the impact that stigma has on their life and learn about information and techniques to manage any distress relating to this. It is hoped that it will be helpful to talk through aspects of stigma with a supportive research assistant. Those allocated to standard care will be offered to receive some stigma resources included in the appendix of the Let's Talk workbook after the final research assessment at 6 months. It is possible that talking about some of the issues raised during the assessment and the Let's Talk Programme sessions may be upsetting. Participants can decide not to answer a question, stop the assessment or session, or withdraw from the study at any point.

Where is the study run from?
The Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2018 to May 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Melissa Pyle
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Study website
https://www.psychosisresearch.com/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300859

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49902, IRAS 300859

Study information

Scientific Title
A peer-delivered intervention to reduce the impact of psychosis stigma and discrimination: a feasibility randomised controlled trial

Study objectives
The aim of this study is to find out if the Let's Talk intervention is helpful, if it is possible to recruit the required numbers of participants, if participants will remain involved in the study, and if they will complete the treatment they are allocated to.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2021, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8253, +44 (0)207 104 8068, +44 (0)207 104 8276; berkshireb.rec@hra.nhs.uk), REC ref: 21/SC/0232

Study design
Randomized; Interventional; Design type: Treatment, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
This will be available at https://www.psychosisresearch.com/ but it is not currently available online at the time of registration

Health condition(s) or problem(s) studied
Psychosis

Interventions
The researchers will conduct a feasibility randomised controlled trial (RCT) across two UK sites, Greater Manchester, and Northeast London. Participants who meet the inclusion criteria will be randomly allocated to either Let's Talk plus treatment as usual (TAU), or TAU alone.
They will randomise participants at the individual level using an independent remote web-based randomisation system (sealed envelope), using randomised-permuted blocks of random size. Randomisation will be in 1:1 ratio stratified by site and delivery mode (in person or remote).
The research assessments will be conducted by raters (blind to allocation) at baseline, end of treatment and 6 months post-randomisation.
A nested qualitative interview study will be conducted to explore the acceptability of the intervention from the perspectives of participants who have received 'Let's Talk' and peer support workers who have delivered it.

Setting/context
Let's Talk is a two-site study conducted in adult secondary care mental health services in Greater Manchester Mental Health NHS Foundation Trust (GMMH) and North East London NHS Foundation Trust.

Assessment schedule
All assessments will be delivered at baseline, 2 months (end of treatment) and 6 months. Participants are given a £10 token of appreciation at each assessment (£30 in total)
Updated 19/01/2022: All assessments will be delivered at baseline, 2.5 months (end of treatment) and 6 months. Participants are given a £10 token of appreciation at each assessment (£30 in total)

Intervention
Let's Talk will be delivered, in addition to TAU, on a one-to-one basis by Peer Support Workers (PSW) over an 8-week intervention window with up to 8 sessions available.
Updated 19/01/2022: Let's Talk will be delivered, in addition to TAU, on a one-to-one basis by

Peer Support Workers (PSW) with up to 10 weeks of the Let's Talk peer support programme available.

The aims of Let's Talk are to: help participants weigh pros and cons of disclosing which vary by setting (e.g., disclosure at one's employment has different costs and benefits than disclosure to one's friendship network); teach relatively safe ways to disclose should the person decide to do so; help people craft stories that reflect their disclosure goals; support participants with internalised stigma and developing affirming self-beliefs. All participants allocated to Let's Talk will receive a copy of the workbook. Sessions with the PSW will be structured around the manual and workbook. Participants will have the option of a Let's Talk booster session that will review disclosure decisions, use of peer support programs, current assessment of pros and cons of disclosure and whether the person's story has changed

Comparator
The control condition is treatment as usual (TAU) which includes EIP and AMH services. All participants in the intervention and comparator arms will have access to one of these services and an identified care coordinator. Let's Talk is not currently available as part of TAU at the recruiting sites. The researchers will not ask referrers to withhold any treatment. Research Assistants will identify any risks to self or others that require immediate action. Participants in both groups will receive a crisis card providing emergency contact details and all participants will have an allocated care coordinator. All routine or additional treatments in both conditions will be monitored.

Intervention and trial acceptability: Qualitative interviews
A nested qualitative study will identify key themes associated with the acceptability of the peer-delivered intervention. Individual semi-structured interviews will explore participants' experience of receiving Let's Talk, and identify barriers and solutions to participation, by focusing on e.g. structural issues (access/choice/amenities); process (personalisation, interpersonal quality of care, co-ordination of care) and outcomes (perceived mental and physical well-being). Semi-structured interviews will be conducted after the end of the intervention delivery. Interviews will be conducted face to face. Study participants will be informed of the qualitative interviews at the written informed consent stage via the participant information sheet. Written informed consent will be taken for the use of verbatim quotes. All quotes used will be done so anonymously. This will involve individual interviews with a purposive sample of 15/20 service users who have been randomised to receive Let's Talk. The researchers will purposively sample individuals with differing levels of engagement with Let's Talk. Data will be analysed using thematic analysis, which results in a rich and accessible account of qualitative data (Braun & Clarke, 2006). The researcher makes sense of the data and reports themes that emerge (Braun & Clarke, 2006). They will assume a realist perspective and report the experiences of participants. Themes will be coded inductively at a manifest level to inform the design of a future trial and refine the peer support intervention. Coding will be conducted systematically and iteratively.

Plan of investigation and timetable:
Prior to start of the study the researchers will: a) obtain ethics and research governance approvals (b) recruited and trained the members of staff (peer support workers and research assistant). The project will be delivered over a 23-month period. In months 1-15 the researchers will recruit participants into the study (total n = 75; total n for GMMH = 65; total n for NELFT = 10). Months 1-17 is the intervention phase. Months 3-17 is the end of treatment assessment phase. Months 7-21 is the 6-month follow-up phase. Months 3-21 is the nested qualitative interview phase. The final report would be written up in months 22-23.

Project management
Greater Manchester Mental Health Foundation Trust will be the primary sponsor. In accordance with high standards of research governance the researchers would ensure researchers receive training in the International Conference on Harmonisation (ICH) Guidelines - Good Clinical Practice before recruitment commences. The project will be trial managed by Dr Melissa Pyle, who is an experienced trial manager for NIHR funded trials.

Data management
Each study participant will be assigned a unique trial identification number at the start of the assessment process. This number will be written on all clinical assessment forms/datasheets and databases used to record data on study participants, this will be the research register. A hard copy of a record sheet linking patient identity, contact details and trial identification number for all participants will be kept in electronic format on a secure NHS drive, password protected and only accessible to the research team, and in paper format kept locked in an NHS cabinet on NHS premises which are only accessible to the research team. The research register will be separate from the research data.
The research data will not contain any personally identifiable information and will be identified only by the unique trial identifier. The research data will be stored securely and confidentiality in an NHS cabinet on NHS premises which are only accessible to the research team. The research assistant will enter the data onto an electronic database, which will be stored on a secure NHS drive only accessible to the research team. All data will be kept secure at all times and maintained in accordance with the requirements of the Data Protection Act, and archived according to clinical trial GCP regulations.

Data analysis
All main analyses will be based on the Intention-to-Treat (ITT) principle. Analysis will take place after full recruitment and follow-up. The main focus will be on tabulated and associated graphical summaries of the key indicators of success of the pilot, including participant recruitment; checks for absence of selective recruitment of participants; baseline balance and participant flow. The researchers will report data in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 extension statement for Pilot and Feasibility trials showing attrition rates and loss to follow-up. Important summary statistics will be the number of participants referred through mental health staff, number of referrals found to be eligible, and number of consenting individuals and recruited individuals to each arm. Numbers for drop-out from the allocated interventions, withdrawal of consent and failure to provide follow-up outcome data will be generated. The researchers will report their feasibility results (recruitment, retention, adherence) overall, in order to inform decisions about the viability of a future definitive trial. However, they will also report their descriptive results and 95% confidence intervals on outcome measures by group. This will include checking responses and administration methods for the Economic Patient Questionnaire.

Intervention Type
Behavioural

Primary outcome measure
As a feasibility RCT, a single primary outcome is not meaningful. The key outcomes to inform a definitive trial are:
1. Referral rates: the number of referrals received relative to the number randomised into the trial over the recruitment window
2. Recruitment as assessed by the proportion of eligible participants recruited into the study over the recruitment window

3. Attendance at the Let's Talk programme sessions measured by the session record for each participant allocated to the intervention arm of the trial at end of treatment (2.5 months)
4. Fidelity to the Let's Talk programme manual and principles of peer support as measured by the Let's Talk Fidelity Scale and using the Peer Support Principle-Based Fidelity Index at end of treatment (2.5 months)
5. Most used Let's Talk strategies as assessed by the proportion of strategies recorded in individual Let's Talk session records completed after each session
6. Follow-up/questionnaire response rate as assessed by the proportion of questionnaires completed at 2.5 months (end of treatment) and 6-month follow-up

Updated 19/01/2022: The end of treatment timepoint was changed from 2 months to 2.5 months.

Secondary outcome measures
1. Experienced, perceived, and internalised stigma assessed using the Semi-structured Interview Measure for Stigma in Psychosis (SIMS) at baseline, 2.5 months follow-up and 6 months follow-up
2. Disclosure related distress assessed using a single item question rated on a 1-7 Likert Scale at baseline, 2.5 months follow-up and 6 months follow-up
3. Stigma stress assessed by the 8-item Stigma Stress Scale at baseline, 2.5 months follow-up and 6 months follow-up
4. Recovery assessed using the Process of Recovery Questionnaire at baseline, 2.5 months follow-up and 6 months follow-up
5. Depression assessed using the Calgary Depression Rating Scale for Schizophrenia (CDSS50) at baseline, 2.5 months follow-up and 6 months follow-up
6. Anxiety assessed using the Social Interaction Anxiety Scale (SIAS) at baseline, 2.5 months follow-up and 6 months follow-up
7. Quality of life assessed by the Manchester Short Assessment of Quality of Life Scale at baseline, 2.5 months follow-up and 6 months follow-up
8. Empowerment measured using the Rogers Empowerment Scale (RES) at baseline, 2.5 months follow-up and 6 months follow-up
9. Help-seeking and service utilisation/engagement assessed by an economic patient questionnaire at baseline, 2.5 months follow-up and 6 months follow-up
10. Health status evaluated using the EQ5D at baseline, 2.5 months follow-up (end of treatment) and 6 months follow-up
11. Internalised shame measured using the Internalised Shame Scale at baseline, 2.5 months follow-up and 6 months follow-up
12. Self-esteem measured using the Self-Esteem Rating Scale - Short form at baseline, 2.5 months follow-up and 6 months follow-up

Updated 19/01/2022: The 2 months follow-up timepoint was changed to 2.5 months follow-up.

Overall study start date
16/11/2018

Completion date
31/05/2023

Eligibility

Key inclusion criteria

1. Age 16+ years
2. Meet ICD-10 F20-F29 Schizophrenia spectrum diagnosis, or be receiving services from Early Intervention Services (EIS)
3. Under the care of a mental health service with a care coordinator
4. Competent to provide written, informed consent (for ethical considerations)
5. At least a moderate level of self-reported disclosure-related distress screening scale (Rüsch et al., 2014), as determined by scoring >3 on the screening item
6. At least moderate levels of internalised stigma as determined by a a score of ≥3 on at least one of the Internalised Stigma domains the Semi-structured Interview Measure of Stigma (Wood et al., 2016)

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 75; UK Sample Size: 75

Total final enrolment
70

Key exclusion criteria
1. A primary diagnosis of alcohol or substance dependency (ICD-10 F10 – F19 diagnosis), where this is clearly the cause of their psychotic symptoms. This does not exclude people who use substances or alcohol, only those with a primary diagnosis. This will be confirmed by the participant's care coordinator or psychiatrist
2. A diagnosis of moderate to severe learning disability, as confirmed by the participant's care coordinator or psychiatrist
3. An ICD-10 diagnosis of organic psychosis, as confirmed by the participant's care coordinator or psychiatrist
4. Non-English speaking, where this prevents engagement in informed written consent and interviews
5. Immediate risk to self or others as confirmed by the participant's care coordinator or psychiatrist

Date of first enrolment
01/09/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Prestwich Hospital
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
CEME Centre
North East London NHS Foundation Trust
West Wing
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Sponsor details
Prestwich Hospital
Bury New Road
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United Kingdom
M25 3BL
+44 (0)161 358 1689
ResearchOffice@gmmh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR 200460

Results and Publications

Publication and dissemination plan
1. The study protocol is not currently available online
2. The Statistical Analysis Plan will be available on the Clinical Trials Unit website but is not published at present
3. Planned publication in a high-impact peer-reviewed journal within 1 year of the overall trial end date

Intention to publish date
31/05/2024

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon reasonable request from Dr Melissa Pyle (melissa.pyle@gmmh.nhs.uk). Datasets will be available once the primary outcome paper has been published. Participant-level data for each outcome will be pseudo-anonymised. Requests for data must include the proposed research questions, hypotheses and statistical analysis plans. Requests that do not overlap with planned analyses by the research team will be considered.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Results article		27/12/2024	17/01/2025	Yes	No