ISRCTN67429289 https://doi.org/10.1186/ISRCTN67429289

A peer support programme to help adults with psychosis talk about mental health and reduce stigma

Submission date
30/09/2025

Recruitment status
Recruiting

Registration date
20/10/2025

Overall study status
Ongoing

Last Edited
20/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aim
People who experience psychosis often face stigma and discrimination, which can negatively affect how they consider themselves and their identities. This is referred to as 'internalising' stigma. This can cause serious problems with self-esteem, cause depression and anxiety, and lead to withdrawal from others, study or work.

To help people with psychosis feel less troubled by 'internalised stigma', mental health researchers in Manchester adapted an American intervention into a new intervention called 'Let' s Talk'. A small trial was conducted to test this intervention. Let's Talk involved Peer Support Workers (PSWs), who also have experience of psychosis, meeting with people taking part in the trial (Peers). PSWs and Peers discussed mental health stigma, and how to talk about mental health difficulties with others. Many sessions focused on helping Peers understand how to decide whether they want to discuss their mental health difficulties with others, or not. The trial found that people were interested in taking part, that most participants offered the intervention attended the sessions, and most participants attended the research assessments.

A larger trial of Let's Talk is planned to understand more clearly how it can help improve the personal wellbeing of people who experience psychosis. In a larger trial, more participants can be included and more advanced research tests can be run to see what parts of the Let's Talk approach are most helpful. This would help make Let's Talk as effective as possible, and it could then be offered in NHS mental health services.

Who can participate?
People in four UK areas aged 16+ who meet an ICD-11 Schizophrenia or other primary psychotic disorders diagnosis (as determined by the participant's clinical team) or are receiving care for psychosis from Early Intervention Services (EIS), or under the care of a secondary or tertiary mental health service at the point of referral to ensure provision of care. They will also report moderate to severe self-reported disclosure-related distress (scoring >3 on the disclosure

distress screening item), and moderate to severe internalised stigma (scoring of ≥3 on at least one of the Internalised Stigma domains of the Semi-structured Interview Measure of Stigma (SIMS)).

What does the study involve?
Participants will meet with a research assistant (RA), and they will complete a range of questionnaires, including the Questionnaire about the Process of Recovery (QPR). Participants will be randomly allocated (50:50 chance) to either receive the peer-delivered Let's Talk intervention (plus their usual mental health treatment) or receive their usual mental health care alone (TAU). Participants who are allocated to receive the Let's Talk intervention will be offered sessions with a peer support worker over 16 weeks, which will involve completing an 8-module workbook together. Participants will meet with research assistants again at 4 and 12 months to complete the same set of questionnaires.

What are the possible benefits and risks of participating?
If the Let's Talk intervention is found to improve personal recovery outcomes, this could add to the current evidence base for helpful psychological interventions and potentially benefit future mental health services for people experiencing psychosis. A potential risk is that participants may find the research assessment process distressing. Participants will be offered choices around their assessments, including the option of breaks and assessments spread across multiple occasions.

Where is the study run from?
The lead site is Greater Manchester Mental Health NHS Foundation Trust (GMMH). Avon and Wiltshire Mental Health Partnership NHS Trust (AWP), South London and Maudsley NHS Foundation Trust (SLaM) and North East London NHS Foundation Trust (NELFT) are also sites from which the Let's Talk 2 study is run.

When is the study starting and how long is it expected to run for?
May 2025 to August 2028. The study will begin enrolling participants in November 2025 to May 2027. Overall, the study is expected to run for 40 months.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Dr Melissa Pyle, based at Greater Manchester Mental Health NHS Foundation Trust (GMMH), melissa.pyle@gmmh.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Melissa Pyle

ORCID ID
https://orcid.org/0009-0004-5337-9031

Contact details

Greater Manchester Mental Health NHS Foundation Trust
The Psychosis Research Unit, R&I
Central Park Hub, Building B
Northampton Road
Manchester
United Kingdom
M40 5BP
+44 (0)161 271 0084
melissa.pyle@gmmh.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
343302

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 62177, NIHR163493

Study information

Scientific Title
A peer-delivered programme for mental health disclosure distress and internalised stigma (Let's Talk) in comparison to treatment as usual in adults with psychosis: A randomised controlled trial to investigate the efficacy of a peer intervention targeted at stigma-related mechanisms

Acronym
Let's Talk 2

Study objectives
The study objective is to establish Let's Talk's clinical efficacy in a multisite Randomised Controlled Trial (RCT) for adults with psychosis who report moderate to severe Internalised Stigma (IS) and disclosure-related distress; and to assess whether improved measures of personal recovery are mediated via key stigma variables. The objective is to recruit 352 participants to detect a target difference of 4.5 points on the QPR.
Eligible participants will be randomised to either the intervention arm (Let's Talk + Treatment as Usual (TAU)) or the control arm (TAU alone). Participants allocated to the intervention will be offered up to 16 sessions over a four-month intervention window with up to one booster session. Outcome data will be collected at baseline, at 4-month assessment (end of treatment) and at 12-month assessment (12 months post-randomisation). The study will determine whether the treatment effect on recovery is mediated by key mechanisms targeted in the intervention: (1) reduced IS (primary mechanism), (2) reduced stigma stress (degree to which perceived stigma is exceeded by personal coping resources for stigma) and (3) reduced disclosure distress.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 16/09/2025, Cambridge South Research Ethics Committee (Equinox House, City Link , Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8115; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0718

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia, schizotypal and delusional disorders

Interventions
Design
A clinical efficacy randomised controlled trial (RCT) will be conducted across 4 NHS secondary or tertiary care mental health services in the UK: Avon and Wiltshire, Greater Manchester, North East London, and South London. Participants who meet all inclusion criteria and no exclusion criteria will be randomly allocated to either Let's Talk plus treatment as usual (TAU), or TAU alone. Participants will be randomised at the individual level via a Clinical Trials Unit (CTU)-hosted, web-based system using random permuted blocks. Randomisation will be at a 1:1 ratio, stratified by site. Outcome and mediational variables will be collected in research assessments at baseline, 4 months (end of treatment) and 12 months post-randomisation. The assessments will be conducted by raters who are blind to participant allocation.

Clinical efficacy aims
1. To establish the efficacy of Let's Talk + TAU in improving personal recovery (primary outcome) when delivered to adults with psychosis who report moderate to severe internalised stigma and disclosure-related distress compared to TAU alone.
2. To establish the efficacy of Let's Talk + TAU on secondary outcomes of improving quality of life, reducing depression, and reducing social interaction anxiety compared to TAU alone.

Clinical efficacy hypotheses
1. Let's Talk plus TAU will result in improved measures of personal recovery at the end of treatment (4-month follow-up; primary outcome) and 12-month follow-up compared to TAU alone.
2. Let's Talk plus TAU will result in improved quality of life at the end of treatment (4-month follow-up) and 12-month follow-up compared to TAU alone.
3. Let's Talk plus TAU will result in a reduction in the level of depression and social interaction anxiety at the end of treatment (4-month follow-up) and 12-month follow-up.

Mechanistic aims
1. To examine the extent to which Let's Talk plus TAU impacts on measures of personal recovery via a decrease in stigma-specific processes (Internalised stigma [IS], stigma stress, and disclosure distress).

Mechanistic hypotheses
1. Let's Talk + TAU will lead to reductions in IS and stigma stress
2. The mechanisms by which Let's Talk + TAU lead to improvements in personal recovery are due to reductions in IS, stigma stress and disclosure distress.

Primary outcome
The primary outcome will be the total score on the 15-item Questionnaire about the Process of Recovery (QPR) at 4-month follow-up. The QPR was developed in collaboration with patients to assess personal recovery from psychosis, containing items that were initially derived from qualitative interviews about this topic. It has excellent reliability, validity, and sensitivity to change and is nationally adopted as a PROM for evaluation of early intervention for psychosis services, forming part of the Mental Health Services Data Set. Patients consistently prioritise personal recovery over specific symptom change, and the QPR has been cited as the only measure of recovery that directly maps onto all 5 processes of the influential CHIME framework of personal recovery.

Secondary outcomes
Secondary outcomes will assess relevant dimensions of psychiatric distress and quality of life.
1. The Social Interaction Anxiety Scale (SIAS), a 20-item self-administered scale questionnaire, which reflects anxieties people may encounter in social situations. Items are rated on a 5-point scale from 0 (not at all) to 4 (extremely). The SIAS is a reliable and valid measure, with initial testing demonstrating high levels of internal consistency and test-retest reliability.
2. Depression will be measured using the Patient Health Questionnaire-9 (PHQ-9), a validated, nine-item, patient-reported outcome measure (PROM). The PHQ-9 is a brief self-administered scale which reflects the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, fifth edition) criteria. It classifies current symptoms on a scale of 0 (not at all) to 3 (nearly every day).
3. The DIALOG scale is a validated, 11-item, patient-reported outcome and experience measure (PROM/PREM). The DIALOG scale assesses eight life domains (mental health, physical health, job situation, accommodation, leisure, partner/family, friendship, personal safety) and three treatment aspects (medication, practical help, meetings with healthcare professionals). The items are rated on a 7-point scale from "totally dissatisfied" to "totally satisfied" with the value 4 representing a neutral "in the middle."
4. The Psychotic Symptoms Rating Scale: Multimodal Hallucinations, an unpublished scale adapted from the PSYRATS: Auditory Hallucinations subscale for assessing the presence and impact of nonauditory hallucinations.
5. The Revised Green et al Paranoid Thoughts Scale (R-GPTS), a reliable measure of paranoia comprising two subscales to assess ideas of reference (Part A; 8 items) and ideas of persecution (Part B; 10 items), over the past month. The two subscales are designed to be treated as distinct measures and should be scored separately. A total score for each subscale is obtained by adding together the items. Items are scored on a 4-point scale from 0 (Not at all) to 4 (Totally).

Mechanistic outcomes
The proposed mechanisms of action for Let's Talk will also be measured with the following instruments:
1. The Semi-structured Interview Measure for Stigma in Psychosis (SIMS), which assesses experienced, perceived, and internalised stigma.
2. Stigma stress will be assessed by the 8-item Stigma Stress Scale.
3. Disclosure-related distress will be assessed using a single item from the Disclosure Distress Scale.

Assessment schedule
Research assessments comprising the above measures will be completed at baseline, 4 months (end of treatment) and 12 months post-randomisation. Participants will receive £25 on completion of each research assessment as a token of appreciation for their time (£75 total).

Treatment condition (Let's Talk + TAU)
Let's Talk will be delivered, in addition to TAU, on a one-to-one basis by Peer Support Workers (PSWs). A 4-month treatment window permits ≤16 sessions, with an option for 1 booster session to consolidate gains. The expectation for delivery is in-person, but the intervention can be delivered remotely via video call or telephone as a contingency. 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. Sessions with the PSW will be structured around the Let's Talk manual and workbook, which have been refined based on qualitative feedback from participants and PSWs in the Let's Talk feasibility RCT. All participants allocated to Let's Talk will receive a copy of the workbook. All routine or additional treatments in the comparator arm will be monitored.

Comparator condition (TAU)
The control condition is treatment as usual (TAU). All participants in the intervention and comparator arms are required to be under the care of a secondary or tertiary care mental health service as a condition of inclusion. In the UK, TAU for psychosis is based on the Care Programme Approach and typically includes psychiatric medication, assignment of community-based health and social care staff, care coordination, access to rehabilitative services, and outpatient care. Referrers for participants in the TAU arm will not be requested to withhold any treatment throughout the duration of the trial, and all routine or additional treatments will be monitored. Except for emergent risk issues, TAU alone will also not involve liaison between researchers and the participants' healthcare teams. Research Assistants will identify any risks to self or others that require immediate action. All routine or additional treatments in the TAU arm will be monitored.

Intervention Type
Behavioural

Primary outcome(s)
Personal recovery will be measured using the total score on the 15-item Questionnaire about the Process of Recovery (QPR) at 4 months

Key secondary outcome(s))
The following secondary outcome measures will assess relevant dimensions of psychiatric distress and quality of life at baseline, 4 and 12 months:
1. Social anxiety will be measured using the Social Interaction Anxiety Scale (SIAS)
2. Depression will be measured using the Patient Health Questionnaire-9 (PHQ-9)
3. Satisfaction in multiple life domains and in treatment aspects will be measured using the DIALOG
4. Paranoia will be measured using the revised Green et al. Paranoid Thoughts Scale (R-GPTS)
5. The presence and impact of non-auditory hallucinations will be assessed using The Psychotic Symptoms Rating Scale: Multimodal Hallucinations. This is an unpublished scale adapted from PSYRATS-AH.

The proposed mechanisms of action for Let's Talk will also be measured with the following instruments at baseline, 4 months and 12 months:
1. Experienced, perceived, and internalised stigma will be measured using the Semi-structured Interview Measure for Stigma in Psychosis (SIMS)
2. Stigma stress will be assessed by the 8-item Stigma Stress Scale (SSCI-8)
3. Disclosure distress will be measured using the single-item Distress Disclosure Index (DDI)

Completion date
31/08/2028

Eligibility

Key inclusion criteria
1. Age 16+
2. Meet ICD-11 Schizophrenia or other primary psychotic disorders diagnosis (as determined by the participant's clinical team) or be receiving care for psychosis from Early Intervention Services (EIS) to account for diagnostic uncertainty in the early stages of psychosis.
3. Under the care of a secondary or tertiary mental health service at point of referral to ensure provision of care.
4. Able to provide written, informed consent (for ethical considerations).
5. Willing to engage in a peer support intervention.
6. Moderate to severe self-reported disclosure-related distress as determined by scoring > 3 on the disclosure distress screening item.
7. Moderate to severe internalised stigma as determined by a score of > = 3 on at least one of the Internalised Stigma domains of the Semi-structured Interview Measure of Stigma.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. A primary diagnosis of alcohol or substance dependency, 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 participants' care teams.
2. A diagnosis of moderate to severe learning disability. This will be confirmed by participants' care teams.
3. An ICD-11 diagnosis of organic psychosis. This will be confirmed by participants' care teams.
4. Language barriers that are an obstacle to participation, since we are unable to provide translation of the intervention workbook or interpreters during intervention sessions.

5. Immediate risk to self or others. This will be confirmed by participants' care teams.
6. Currently receiving structured, individual psychological therapy.

Date of first enrolment
01/11/2025

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

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

Study participating centre
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

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

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill

Bath
United Kingdom
BA1 3QE

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	08/09/2025	16/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	22/09/2025	16/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes