LET'S TALK 2

NHS
Greater Manchester
Mental Health
NHS Foundation Trust

STUDY PROTOCOL

Full Study 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 internalised stigma related mechanisms.
Short Study Title:	Let’s Talk 2
Protocol Version:	2.0
Protocol Date:	22/SEP/2025
Funder:	National Institute for Health and Care Research (NIHR) Efficacy and Mechanisms Evaluation (EME)
Funder Reference:	NIHR163493
IRAS Number:	343302
Sponsor ID:	x812s
ISRCTN Number:	[TO BE INSERTED HERE]
CPMS Number:	62177
Chief Investigators:	Professor Tony Morrison and Dr Melissa Pyle

Contents

1. Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I understand that a clean copy of the study protocol will be published by the funder on fundingawards.nihr.ac.uk. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

Name (please print):

Position:

Joint Chief Investigators:

Signature: Date: 29/SEP/2025

Name: (please print): MELISSA PYLE

Signature: Date: 29/SEP/2025

Name: (please print): TONY MORRISON

2. Summary of protocol amendments

All changes summarised below have been approved by the funder (NIHR EME), the Research Ethics Committee (where relevant) and the Health Research Authority (where relevant).

Category	Summary	Protocol version # and date	Amendment #
Exclusion criteria	Exclusion criteria updated Changed from "non-English speaking, since the intervention workbook has been adapted for individual delivery in English and is a talking therapy which would require both translation (workbook) and interpreters during the intervention session. Provision for non-English speakers would not be feasible within the scope of this controlled test of intervention efficacy as the intervention workbook has been developed and tested for feasibility in English." TO "Language barriers that are an obstacle to participation since we are unable to provide translation of the intervention workbook or an interpreter during the intervention session"	V 2.0 22/SEP/2025	NSA001
Recruitment approaches	Update to include, "We will also utilise existing opt-in and/or opt-out methods for participant identification and recruitment, as approved by individual	V 2.0 22/SEP/2025	NSA001

	participating NHS Trusts. We will also accept referrals from research staff working on different research studies at all 4 recruiting sites who identifies a potential participant for Let's Talk 2.”		
Assessment of safety	Update to include, “However, prior to receiving ethical and regulatory approvals, the sponsor agreed that SAEs may be reported within five working days of the CI becoming aware of them (rather than 24 hours, as is usually the case for GMMH-sponsored studies under RDSOP41). The rationale for the extended reported timeline discussed with the sponsor is firstly that Let’s Talk 2 is considered to have a low risk profile, being a non-CTIMP (Clinical Trial of an Investigational Medicinal Product) study, and the feasibility trial Let’s Talk having a low SAE rate. Secondly, the extended reporting timeline will allow sufficiently thorough information-gathering and discussion to decide upon severity, relatedness and expectedness of SAEs that arise.”	V 2.0 22/SEP/2025	NSA001

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Funder	National Institute for Health Research (NIHR) Efficacy and Evaluation Mechanism Programme

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4. Abbreviations

Adverse events	AE
Black, Asian and Minority Ethnic	BAME
Clinical Trial of an Investigational Medicinal Product	CTIMP
Clinical Trials Unit	CTU
Data Monitoring and Ethics Committee	DMEC
disclosure distress scale	DDS
Honest, Open, Proud	HOP
Internalised Stigma	IS
Lived Experience Advisory Forum	LEAF
Minimal Important Difference	MID
National Institute for Health and Care Excellent	NICE
Participant Information Sheet	PIS
Patient and Public Involvement	PPI
Patient reported outcome measure	PROM
Patient Health Questionnaire-9	PHQ-9
Peer Support Worker	PSW
Questionnaire about the Process of Recovery	QPR
Randomised Controlled Trial	RCT
Semi-structured Interview Measure of Stigma	SIMS
serious adverse event	SAE
Service User Reference Group	SURG
Social Interaction Anxiety Scale	SIAS
Treatment as Usual	TAU
Trial Management Group	TMG
Trial Steering Committee	TSC

5. Abstract

Research question: Our study will answer the primary question, what are the treatment effects of the internalised stigma (IS) targeted, peer-delivered intervention Let's Talk + treatment as usual (TAU) for improving personal recovery compared to TAU in people with psychosis who report moderate to severe IS? The secondary research question is, do the key mechanisms of reduced IS, reduced stigma stress and reduced disclosure related distress mediate the treatment effects of Let's Talk on improved personal recovery?

Background: Psychosis is a serious mental health condition. Standard treatment typically includes antipsychotic medication, which targets psychiatric symptoms. However, recovery from psychosis is not limited to the reduction of psychiatric symptoms, but is a personal process involving rebuilding life, rebuilding self and hope. Psychosis is highly stigmatised with pernicious stereotypes and high rates of discrimination. A harmful consequence of stigma is IS, which is associated with reduced personal recovery. A group based, peer intervention called Honest, Open and Proud (HOP) shows promise in reducing stigma related variables. We conducted a feasibility Randomised Controlled Trial (RCT) of an adapted version of HOP, renamed Let's Talk, which allows for individual delivery to people with psychosis by peer support workers (PSW) in the NHS. The RCT showed it is feasible and safe to conduct a RCT of the intervention. Although not powered to detect treatment effects we found small effects at end of treatment and 6-month follow-up for improved personal recovery, moderate effects for reduced IS at end of treatment and large effects for IS at 6-month follow-up. The minimal important difference for the Questionnaire about the Process of Recovery (QPR) is a 4–5-point increase. For the feasibility RCT, we observed a mean difference of 4 points at end of intervention. A clinical efficacy trial is now required.

Aims/objectives: To establish Let's Talk's clinical efficacy in a multisite RCT for adults with psychosis who report moderate to severe IS; 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, who will be randomised to Let's Talk + TAU or TAU.

Methods: Participants will be recruited from NHS services across 4 UK sites. Primary outcome is total score on the QPR. Secondary clinical outcomes are depression, social anxiety, psychosis symptoms and quality of life. The primary outcome will be analysed using a repeated measures mixed effect model accounting for baseline score, design covariates, nominal time, and treatment-by-time interaction, with participant and PSWs as random effects. The treatment window will be 4 months with mediational and outcome variables collected at baseline, 4-month follow-up and 12-month follow-up. The project will be delivered over 40 months.

Anticipated impact/ dissemination: The study will investigate the clinical efficacy of a novel intervention deliverable in the NHS. Long-term benefits include improving the efficacy/accessibility of evidence-based psychosocial interventions for people with psychosis, responding to the NHS's Long-term Plan for implementing a peer workforce with a targeted intervention. Dissemination will occur via peer-reviewed articles, conference presentations, participant feedback, the intervention manual and workbook, and engagement with the service-users.

5. Background and rationale

5.1. Why is the research needed now?

5.1.1. Internalised stigma as a barrier to recovery for adults with psychosis.

Psychosis is a serious mental health condition that involves people experiencing cognitive, behavioural, and perceptual changes such as hearing or seeing things that others do not (hallucinations) and/or holding beliefs that are not based on reality (delusions), which can be highly distressing.

Standard treatment for psychosis typically includes antipsychotic medication, which targets the psychiatric symptoms of psychosis outlined above. However, recovery from psychosis is not limited to the reduction of psychiatric symptoms, but is a personal process involving rebuilding life, rebuilding self, and hope for a better future (1). The National Institute for Health and Care Excellent (NICE) Guideline (CG178) emphasises personal recovery as a key outcome for service users (2), and service user with psychosis echo the importance of personal recovery and recovery-orientated interventions (3,4).

The Lancet have very recently brought an international spotlight to the global need to end stigma of mental health conditions and the harmful consequences that arise because of it (5). Psychosis is highly stigmatised with pernicious stereotypes (6, 7) and high rates of discrimination (8), and as such, stigma is direct challenge to the process of rebuilding life, self and a hope for a better future (9). A harmful consequence of public stigma is internalised stigma (IS), which occurs as an understandable reaction to stigma whereby stigma beliefs (e.g., incompetence) or emotions (e.g., shame) are assimilated into self-identity (10). This can impact the pursuit of life goals (11) and lead to disclosure concerns including self-concealment and withdrawal from social life and relationships (12). Whilst personal recovery is a priority to people with psychosis (3), NHS services (2) and UK health policy (13), stigma acts as a barrier to recovery (14). Around 41% of people with psychosis experience at least moderate levels of IS (15), which is associated with increased depression (14,16), social anxiety (14, 17, 18), self-harm, and suicidality, and worsening of symptoms of psychosis (14).

It is argued that, because IS arises as a consequence of a social injustice (i.e., stigma), locating delivery of interventions for IS with clinicians may unintentionally pathologise IS as a problem located in the individual (19). However, peer support, delivered by people with lived experience of a condition that have high levels of personal recovery, is well placed as an intervention that targets IS with peer principles of hope and optimism about personal recovery (20). This aligns well with the emphasis CG178 places on psychosis services providing care in the ‘least stigmatising environment and in an environment of hope and optimism’ (2). A meta-analysis of data from three trials of individually delivered peer support with a total sample size of 593 people with serious mental health problems, showed a statistically significant benefit of peer support in comparisons to TAU in the small effect size range (smd=0.22; 95% CI 0.01, 0.42, p=0.042) over a 12-18 month follow-up (21). Further, the UK Government’s vision for the future of mental health services includes an established PSW workforce (13), but evidence is required for stigma targeted, peer-delivered interventions which improve personal recovery (5).

In summary, psychosis is a serious mental health condition affecting 1 in every 100 people (22) and incidence data shows that rates of psychosis are increasing with new cases of first-episode psychosis rising to 11,067 per annum in the UK by 2025 (23). Schizophrenia and other psychoses are one of the top 25 causes of disability worldwide (24) and stigma has been shown to have a negative economic impact and it is argued that interventions that reduce stigma and harmful consequences may confer economic as well as personal benefits (25). Based on the population statistics from the 2021 census (26) at least 564,898 in England currently experience psychosis, true rates are likely to be higher since the 1% estimate of psychosis this is drawn from the Adult Psychiatric Morbidity survey (22), excluding people currently in hospital, prison, homeless or in sheltered accommodation and a significant proportion of these, at 41.7% (15) will internalised stigma to at least a moderate extent. An IS targeted intervention that and reduces IS could lead to significant improvements in personal recovery; if personal recovery is improved and sustained, it will have long-term economic benefit by reducing long-term treatment needs and improving health.

5.1.2. What is the knowledge gap this research will address?

PSWs provide a credible role model for personal recovery and can challenge stereotype legitimacy (27, 28) and peer support can lead to small but statistically significant improvement in personal recovery (21).

However the quality of the available trials of individually delivered peer support is low to moderate quality, do not demonstrate the mechanisms of action on outcomes and the number of available trials which focus on personal recovery for people with psychosis are limited (19). CHIME (4) is a conceptual framework for recovery that includes five recovery concepts: connectedness; hope and optimism; identity, (positive self-identity); meaning and purpose (real things to do, places to go, goals to achieve); and, empowerment i.e., control over life, focusing on strengths, making decisions, taking personal responsibility. IS is negatively associated with hope and dimensions of empowerment (14).

In answering the question of how to reduce IS, data from two meta-analyses of psychosocial interventions show encouraging signals for psychosocial approaches, including peer-led approaches but concluded that studies were limited by small sample sizes and lack of methodological robustness (29, 30). One psychosocial, peer-led approach that shows promise is the Honest, Open, Proud (HOP) programme, which is a group-based, peer-led intervention to aid mental health disclosure decision-making and address IS (31, 32). Because of stigma, decisions regarding disclosure of mental health experiences can be difficult (33). Engaging in social coping mechanisms to conceal a diagnosis from family, friends and wider social networks is a strategy used to manage stigma (34), but one that can result in anxiety and fear of being ‘found out’ (28), with distress regarding decision-making uncertainties of *‘if*, *when and how’* to disclose (31). Secrecy regarding diagnosis and social withdrawal, because of stigma, contribute to IS for people with psychosis (34). Conversely, successful disclosure can increase access to supportive social relationships and reduce social stigma (33). HOP’s theory of change suggests that supporting disclosure decisions can reduce internalised stigma stress and stigma stress (32). A number of clinical trials have provided evidence for HOP’s theory of change, with a meta-analysis of HOP trials showing a significant, medium effect size for reduced stigma stress and a significant, small effect size for reduced IS at follow-up (35). Reduction in stigma stress has been shown to be one mechanism by which HOP improves outcomes of IS, depression and quality of life (36).

Despite the promise of HOP, the evidence base remains in development with a small number of RCTs and no formal evaluation of personal recovery outcomes. The Lancet Commission on stigma emphasised how most interventions for IS, such as HOP, have been group based and that this can create a barrier for people who are not willing to disclose a mental health intervention (5), and some HOP studies report difficulties with recruitment which may be due to the group delivery (35). Individual delivery of HOP by PSW would not only provide an opportunity to engage people with psychosis who are not willing, or unable, to attend a group, but also provide an opportunity to build a trusting relationship with a PSW over time, which has been shown to increase personal recovery (21).

The NIHR have recognised the importance of addressing IS for people with psychosis with a commissioned call (HTA 17/124). Our application to the call was rejected after the Stage 2 funding board meeting. The rejection letter provided the following guidance: “The Board was concerned about the feasibility of rolling-out this intervention in the NHS in this patient group. The board were concerned about the delivery of this intervention by PSWs and the vulnerability of both workers and patients.” There remains a knowledge gap regarding effective, safe interventions to reduce internalised stigma and in response, our research group was funded via NIHR RfPB to adapt the HOP intervention for individual delivery by PSW for people with psychosis. For our feasibility trial the name HOP was changed to Let’s Talk through patient and public involvement (PPI) consultation. The results of our feasibility RCT address the HTA board’s concerns. Let’s Talk was a feasibility randomised controlled trial (RCT) of individually delivered HOP (Let’s Talk) by PSWs compared to treatment as usual (TAU). Follow-up was 2.5 (end of intervention) and 6-month follow-up. Up to 10 sessions of the intervention over 10 weeks were offered, plus one booster session. The primary outcome was feasibility data (recruitment, retention, intervention attendance). 149 patients were referred to the study and 70 were recruited. 35 were randomly assigned to Let’s talk + TAU and 35 to TAU. Recruitment was 93% of the target sample size of 75 participants. Retention rate was high (81% at 2.5 months primary endpoint), as was intervention attendance (94% adherence to minimal number of two sessions; 62% attended six or more sessions). There were no emergent safety concerns: for participants allocated to the intervention arm 6/35 (17%) had one or more serious adverse event (SAE), 9 events in total. For context, as detailed below, two of these events took place post consent but before randomisation to the intervention arm, and one event was prior to first intervention session. Of those allocated to the intervention arm the breakdown of SAEs are: voluntary admission to a psychiatric inpatient unit (n=2), involuntary admission to a psychiatric inpatient unit (n=2; 1 of which was post consent but before randomisation), serious violent incident as a the victim (n=2), serious violent incident as the perpetrator (n=1), potentially life-threatening self-harm (n=1; no intervention session had taken place at time of event), and a suicide attempt (n=1; this was before randomisation). In the TAU arm 3/35 (9%) participants had one more SAE with 6 SAEs in total. Breakdown of SAEs in the TAU arm: suicide attempt (n=3), death due to physical health causes (n=1), voluntary admission to a psychiatric inpatient unit (n=2). Of the 15 SAEs, 14 were judged by the independent Trial Steering Committee and Data Monitoring and Ethics Committee (TSC-DMC) not related to trial involvement. One potentially life-threating self-harm event was deemed partially related; the participant and care team reported the event occurred because of an increase in distressing psychosis symptoms, but that some of the research assessment questions were upsetting. To note, the event took place during the baseline period and pre-randomisation. For the adverse events AEs, all events were expected and unrelated. We report full AE and SAE data as allocated and as treated in the primary outcome paper attached.

The feasibility trial was not designed to answer the question of efficacy and an adequately powered RCT is now required. We propose the next step, in line with the Medical Research Council framework for developing and evaluating complex interventions are to conduct an efficacy evaluation of the Let's Talk intervention for people with psychosis, and to identify key mechanistic components of the intervention. We propose a primary outcome of personal recovery measured by the Process of Recovery Questionnaire (QPR) (37), which is a nationally mandated patient reported outcome measure (PROM). The theory of change for the HOP programme is that it targets stigma-related variables of IS and stigma stress through techniques that directly target disclosure related decisions skills and techniques, promoting an informed choice about disclosure (31, 32). The primary mechanistic component for our study is reduced IS. Data from our feasibility trial showed a moderate effect size for reduced IS at end of treatment (38) and the negative relationship between IS and personal recovery has been established (14). Stigma stress is our secondary mechanistic component. Group HOP (35) and individual HOP (38) have shown reductions in stigma stress, and mediating effects of stigma stress on depression and quality-of-life outcomes have been demonstrated (36). Disclosure distress is our third mechanistic component, which is a stigma related variable that is central to HOP theory of change (32). There is indication that group HOP can reduce disclosure related distress at end of intervention and follow-up (39).

5.1.3. Evidence that provides proof-of-concept

Proof of concept evidence for the intervention is drawn from two sources: (1) data from trials of group HOP and pilot data from the Let's Talk feasibility RCT outlined below.

Proof of concept from group HOP studies: A meta-analysis of group HOP trials across adults with mental health conditions, including schizophrenia, adolescents with mental health conditions, suicide attempt survivors and college students found at end-of-treatment, statistically significant effects for SS in the medium effect size range (smd= -0.50, 95% CI -0.87 to 0.14) and non-significant effects for IS in the small effect size range (smd = -0.17, 95% CI -0.39 to 0.05) (35). Regarding clinical outcomes, a non-significant effect for depression in the small effect size range was observed (smd=-0.11, 95% CI -0.30 to 0.05) (35). A meta-regression of the group HOP trials found stigma stress mediated effects of HOP on reduced IS (b= -0.03, p<0.05; total effect: b = 0.12, p<0.01) and reduced depression (b=0.03, p<0.01; total effect: b=0.05, p=0.27) (36).

Pilot data from the Let's Talk feasibility trial: The current research plan is an expansion of the Let's Talk feasibility RCT, which compared the Let's Talk intervention + TAU with TAU alone amongst adults with psychosis. Existing data for individual delivery of HOP is from this trial, which provided signs of efficacy with no emergent safety concerns. Although not powered to detect treatment effects, our preliminary data show small effects for improved personal recovery (2.5 months: *d*=0.31; 95% CI -0.13 to 0.74; 6 months: *d*= 0.27; 95% CI -0.16 to 0.70). The Minimal Important Difference (MID) for the QPR has been calculated to be four points increase on the scale (40). In our study, we observed this MID with a mean difference of four points at end of intervention and 3.61 points at 6-month follow-up. A moderate effect size was observed for reduced IS at end of treatment (*d*= 0.62; 95% CI -1.22 to -0.02), and a large effect at 6 months follow-up (*d*=-1.01; 95% CI -1.62 to -0.41). We found small effects at both time points for reduced stigma stress (2.5 months: *d*=-0.31; 95% CI -0.87 to 0.26; 6 months: *d*=-0.31; 95% CI -8.89 to 0.27). Overall, our data indicate that the Let's Talk intervention may confer clinically meaningful benefits for service user defined recovery. However, data showed that a proportion of participants did not receive the full range of strategies within the intervention workbook, the mean number of days to first session was just over two weeks, and for those who attended less than half the available sessions (<5) the primary reason was non-attendance/cancellation of the session/s. Qualitative feedback from those who received the intervention included the recommendation for a longer period to build the relationship, cover the workbook topics and have an appropriate ending. As such, for this study participants allocated to the intervention will be offered up to 16 sessions over a four-month intervention window.

6. Aims and objectives

6.1. Overall aim

The project will address the following principal research questions:

1. What are the treatment effects of the intervention Let’s Talk + TAU for improving personal recovery compared to TAU in adults with psychosis who report moderate to severe internalised stigma (IS) and disclosure related distress?
2. Do the key mechanisms of reduced IS (primary mechanism) and reduced stigma stress (degree to which perceived stigma is exceeded by personal coping resources for stigma) and reduced disclosure distress mediate the treatment effects of Let’s Talk on improved personal recovery.

6.2. 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, reducing social interaction anxiety and reducing psychosis symptoms compared to TAU alone.

6.3. Clinical efficacy hypotheses

1. Let’s Talk plus TAU will result in improved measures of personal recovery at 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 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 improved clinical outcomes including a reduction in level of depression, a reduction in social interaction anxiety and a reduction in psychosis symptoms at end of treatment (4-month follow-up) and 12-month follow-up

6.4. 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 (IS, stigma stress, and disclosure distress).

6.5. Mechanistic hypotheses

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

6.6. Research objectives

We intend to recruit adults with psychosis who report moderate to severe levels of IS and disclosure related distress. Eligible participants will be randomised to either the intervention arm (Let’s Talk + 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).

We will determine whether 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.

7. Research plan/methods

7.1. Research Design

The study will be an assessor blinded, multisite RCT assessing the efficacy and mechanisms of a psychosocial, PSW-delivered intervention (Let's Talk) for adults with psychosis who experience moderate to severe IS and mental health disclosure related distress. The 2 parallel arms are intervention + TAU (treatment condition) and TAU alone (control condition). Randomisation will be in the 1:1 ratio and stratified by site. On completion of baseline assessments, research assistants (RAs) will perform the randomisation using a web-based service. Our Clinical Trials Unit (CTU), the Centre for Healthcare Randomised Trials (CHaRT; UKCRN registration #7) will independently prepare and hold a randomisation list using random permuted blocks. Assessment of outcome and mediational variables will take place at baseline, at 4 months (end of treatment) and 12 months (post randomisation). In addition to TAU, participants randomised to the treatment arm will be offered up to 16 sessions over a 4-month intervention window with the option of one booster session. Adherence is defined as at least four sessions.

The study will take place across 4 NHS secondary or tertiary care mental health services in the UK: Avon and Wiltshire, Greater Manchester, Northeast London, and South London. Independent, concealed randomisation will be performed via a CTU hosted, web-based system using random permuted blocks, stratified by site.

Our study will include an internal pilot which will commence on 01/11/2025 and end on 30/08/2026. This will allow for 10 months of recruitment, six months of primary outcome data collection (QPR at end of treatment [4-month assessment] and six months adherence data. For recruitment we apply a staged approach in months 1-4: month1 = 2 per site; month 2 = 3 per site; month 3 & 4 = 4 per site; 5 per month thereafter. We will apply three-stage progression criteria (red [stop]/ amber [refine]/ green [go]) (41) to determine the feasibility of progression to the full scale trial, as outlined in Table 1.

Table 1:Three-stage progression criteria for internal pilot

% Threshold*	**Red (stop)**	**Amber (refine)**	**Green (Go)**
Number of sites opened	≤2	3	4
Proportion of target number of participants recruited for the internal pilot period	<60% (n=≤102)	60-99% (n=103-171)	100% (n= ≥172)
Recruitment rate per month per site	<60% (n=≤2.57)	60-99% (n= 2.58-4.2)	100 (n=4.3)
Proportion receiving allocated intervention	<60% (n=≤27)	60-99% (n=28-45)	100% (n=46)
Proportion with complete primary outcome data	<70% (n=≤63)	70-99% (n=64-91)	100% (n=92)

7.2. Population

The study population are adult users of mental health services with psychosis who experience moderate to severe internalised stigma and mental health disclosure related distress.

7.2.1. Inclusion

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 (39).
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 (42).

7.2.2. Exclusion

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 team.
2. A diagnosis of moderate to severe learning disability. This will be confirmed by participants care team.
3. An ICD-11 diagnosis of organic psychosis. This will be confirmed by participants care team.
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 team.
6. Currently receiving structured, individual psychological therapy.

7.3. Withdrawal criteria

Participants who lose capacity to consent will be withdrawn from research procedures associated with the study. A participant is free to withdraw from the trial if they wish to do so, without giving a reason and without affecting their care. A participant who chooses to withdraw from the intervention arm may continue with the research assessments if they wish. The researcher taking the withdrawal information should complete the trial withdrawal form and provide this to the site lead and trial manager to update participant records. Participants who withdraw will not be replaced.

7.4. Recruitment method and consent process

Participants will be recruited through several routes. Research Delivery Network (RDN) funded staff, who have been delegated screening and first contact responsibility by the team leader of a clinical service will offer all service users with psychosis, from that service, the option to complete a stigma survey. This survey will provide important data regarding service users views and experiences of stigma and discrimination. In addition, this portfolio adopted survey will also include basic eligibility screening items for the main trial and a 'consent to be referred' option. This will allow patients with psychosis who meet basic eligibility criteria to opt themselves be referred to the study as part of a self-referral route. We will complete the survey with a minimum of 88 service users per site over the 19-month recruitment window (minimum total n=352). Upon providing this consent to be referred to the study, their basic contact and eligibility information will be shared with the research team who will make contact to discuss the study in further detail and offer the option of an informed consent appointment. In addition, referring healthcare staff will be requested to discuss the study with service-users that meet preliminary inclusion criteria on their caseloads, and to obtain verbal consent from the service user for their referral to the trial. All potential participants will be provided with study information that explains the study rationale (for both healthcare staff and service users). RAs will collect necessary referral information and then make telephone contact with the potential participant to further discuss the study and to arrange a meeting to obtain informed consent. Whenever possible, as part of this initial phone contact RAs will also ask potential participants during this call the single-item disclosure distress scale, therefore avoiding taking up their time with an unnecessary in-person meeting in the event of being ineligible. For any intervention-specific questions, an option will be provided to speak with one of the trial's

PSWs. In the case of self-referrals, RAs will request permission from the service user to contact a named healthcare provider to ascertain eligibility and other relevant referral details. Prior to taking written informed consent, all potential participants will be provided with the participant information sheet (PIS) and given at least 24 hours to consider the information and have any questions they might have answered before providing informed consent. In the initial assessment meeting, RAs will clarify that the randomisation process is fully understood and reiterate that taking part is voluntary. Time will also be taken to address any additional questions/concerns. If the participant is happy to proceed, written consent will be obtained in line with requirements stipulated by the NRES Information Sheets and Consent Forms: Guidance for Researchers and Reviewers, Version 3.6.1 followed by completion of baseline assessments. After eligibility has been confirmed within the trial team, the RA will contact the service user to inform them of the decision. Randomisations will be completed within 2 working days of confirming eligibility. The participant will be contacted by telephone and informed of their allocation which will be followed up with a letter copied to their healthcare professional. In the event of distress or disappointment, an option to speak with a clinically qualified staff member will be made available.

7.5. Type and content of participant information materials

Co-applicants with lived experience of psychosis will produce leaflets, posters and a PIS, utilising materials already employed during our feasibility trial. Additional feedback will be sought from the Psychosis Research Unit (GMMH NHS FT)'s Service User Reference Group (SURG), a panel of ten service users with experience of psychosis, to identify key questions service users may have about the study to ensure important topics are covered within the information materials (e.g., expectations, potential risks/benefits, and other factors influencing informed consent). We will seek guidance on how to address potentially distressing topics appropriately and sensitively (e.g., references to stigma and discriminatory life events). To ensure we develop accessible materials, we will ensure research concepts (e.g., the research blind, randomisation) are explained in simple terms, and we will use readability calculators to ensure total written content is suitable for a broad readership. Our qualitative work to adapt group HOP provided important learning for the research group, grounded in PPI, regarding accessibility of written materials. The recommendations from this qualitative work with PSWs and people psychosis highlighted a number of key principles that will be utilised in developing any written materials for this study: (1) visibly clear demarcations in material, use bold headings and use bullet points for content where possible, (2) allow a space for service users to write down their thoughts/ questions i.e., about the study, (3) ensure the same font and formatting (e.g. bold/underline) is used consistently for headings, subheadings and for the main body of text, (4) ensure colours are suitable for people who are colour blind, (5) use a minimal colour palette, (6) use photo images/simple graphics, (7) produce a large print version for anyone with sight difficulties, (8) Provide a coloured overlay for people with dyslexia , (9) use a readability checker, (10) produce audio formats. We will produce a short video about the study to improve accessibility of study information and an easy read version of the information sheet that can be provided in the first instance. Audio-visual information and easy read summaries will provide a first introduction to the study to cater to a wider range of lower literacy and English proficiency skills. All the written, audio, or visual will be in addition to a skilled RA who from point of contact with the study will facilitate supportive conversations with potential participants about the study. This is in recognition that a conversation may be a preferred mode of accessing information about the study, with written and other information playing a much more supplementary role.

7.6. Overview of research methods to capture and their frequency

Assessment data will be collected by RAs, independent and blinded to allocation, using a self-report questionnaire for the primary outcome measure and a combination of self-report questionnaires and a semi-structured interview for secondary measures and mediational variables. Blinding of the allocation code of a participant will be maintained for Research Assistants (Ras) until all outcomes for that participant have been collected, scored and scoring or data queries resolved. Training for RAs will be developed with the PPI lead and PPI co-applicants with input from our SURG to ensure the RA introduces topics sensitively, ensuring burden is minimised. RAs will receive training to ensure excellent active listening skills with compassion and appropriate empathic responding. Training arrangements will ensure assessor reliability across sites for the Semi-structured Interview Measure of Stigma (SIMS). To aid with this process, assessments may be audio-recorded with participant permission to check on the quality and reliability of the assessment and scores. Audio recording will be conducted in line with the policy and procedures of the NHS site where the recording takes place. After recruitment and baseline assessments are concluded, a follow-up assessment will take place at 4 months post-randomisation (end of treatment). Additional follow-up assessments will be performed at 12 months post-randomisation. A participant may choose to decline the assessment, and this will be recorded as a declined assessment. It is possible a randomised participant may not respond to attempts to complete the follow-up; this will be recorded as lost to follow-up. Follow-up assessments will always be conducted in a manner that supports the participant's wellbeing and choice and as such assessments may be conducted over several visits, include multiple breaks, and will offer participants choice regarding completion of assessment measures i.e., a participant may choose to decline a measure in part or in full. Participants will be contacted by telephone at 8-months post-randomisation for a "keeping in touch" call to promote retention, document potential adverse events, and enquire about wellbeing since previous contact with the RA. The importance of not disclosing treatment condition will be reiterated during this process.

7.7. Study participant support

The Let's Talk feasibility RCT had a low withdrawal rate (5/70; 7%). The approach for the feasibility trial will be replicated here and will centre on minimising burden and ensuring appropriate care and encouragement throughout the assessment process. We have been informed by data from the nested qualitative study from the feasibility trial. Participants reported that the assessment battery was too long and in preparation for this application we have reviewed the assessment battery and include only essential outcome measures, reducing the battery from 12 to nine measures. We have carefully reviewed the options for reliable and valid measures that are shorter in length. We have switched from the MANSA to the Dialog (43) for the assessment of quality of life, and switched from the Calgary Depression Scale to the PHQ-9 (44) for the assessment of depression. Both Dialog and PHQ-9 have the additional benefit of being Patient Reported Outcome Measures (PROMs) for mental health in the UK.

Let's Talk feasibility RCT participants highlighted the importance of a skilled research assistant, commenting RAs were supportive, actively listened, were 'gentle listeners' and promoted participant choice. The RAs and the PSWs for this study will receive training in person-centred support from the study management team, which includes experienced clinical psychologist, and have access to regular supervision with clinically trained staff to ensure that any distress that may arise throughout the assessments is appropriately supported. The following approaches will be taken, including a standardised protocol for managing distress which was developed with our service user reference group: 1) offer a supportive follow-up call with an RA within two working days of the research assessment to discuss any issues that may have arisen for them after completing the measures; 2) offer a 'Helpline Numbers' card that will detail national and local helpline numbers for mental health; 3) order outcome measures in priority; 4) provide a reminder regarding choice to decline questions/measures; 5) offer choice regarding the modality of the assessment (remote or face-to-face) and location of assessments (e.g., an option for least restrictive venues, such as participant homes or primary care settings); and 6) offer choice regarding the timing and length of the assessments, including taking breaks when required and the option of assessments spread across multiple occasions to minimise burden at any one time. All participants will further be provided with contact details for both local and central trial staff in the event of wishing to ask questions or raise concerns throughout the course of their involvement. In the event of participants wishing to drop-out, a range of choices will be offered regarding both intervention and research procedure engagement. If they choose to completely withdraw from the study, then we will consult with their healthcare team to try and ensure continued appropriate support is provided. Existing treatments/services will not be withheld from participants in either arm of the trial as it would not be ethical to do so, and they will be reminded of their right to freely withdraw from the study at any point without affecting their statutory care.

7.8. Methods for sharing study progress and findings with study participants

Our team has a successful record of sharing study findings with participants and will use existing strategies to achieve this. PPI will be integral to developing and implementing study progress and study findings with participants. To ensure maximum connection with participants, we will host updates about the project on the

Psychosis Research Unit website and provide all participants with a link to facilitate continued engagement with the study's progress. As suggested by our Service User Reference Group (SURG) we will ask all participants if they wish to receive a quarterly study newsletter to provide information about the progress of the study recruitment, significant milestones, introducing new staff in their area, and updates on links and resources that participant may find helpful in their local area (signposting). At the end of the trial, we will produce accessible research summaries, which will be produced in easy read format in plain English with info graphics and audio-visual format. Following each assessment, participants will be provided with a thank you card including the Psychosis Research Unit website address and be reminded that updates about the study and the study results will be posted on the website.

7.9. Payments, rewards, and recognition for study participants

Participants will receive a token of appreciation in the form of a thank you card and a £25 payment per research assessment (baseline; 4-months and 12-months; £75 in total). Thank you, cards will also be sent after, the staying connected call at 8 months. We will hold a prize draw for a £50 voucher every 2 months during the 19month recruitment window and survey participants who have completed the survey within that 2-month period will be entered into the prize draw.

7.10. Equality Diversity and Inclusion

The study population meets the definition of an underserved group, in several ways, as specified by the NIHR-INCLUDE guidance. People with mental health conditions are an under-served group (45) and psychosis is a serious mental health condition. Further, people with psychosis are at elevated risk of serious diseases, which is noted as an underserved group, with increased risk of diabetes, cardiovascular disease and respiratory problems and reduced life expectancy (46, 47). Regarding social and economic factors, people with psychosis are at high risk of experiencing stigma and discrimination (4) and our intervention targets the harmful effects of public stigma including IS, stigma stress and lowered empowerment. Data from our feasibility trial shows that most participants were either unemployed, a carer not currently in paid work, or in voluntary work (47/70; 67%), indicating that our feasibility trial was inclusive of people who are from an unemployed or low-income background.

As recommended by the INCLUDE Ethnicity Framework (48) we have considered the characteristics of the population our trial will include and research shows that in the UK some people from Black, Asian and Minority Ethnic (BAME) groups are at higher risk of experiencing psychosis. Compared to the risk of psychotic disorders in the White British population, people of Black African, Back Caribbean and Pakistani origin had a three to five-fold increased risk of experiencing psychosis (49). In designing the study we have considered the Trial Forge Guidance 3 (50) as outlined below.

7.10.1. Eligibility criteria and referral pathways & Building Trust with community organisations

The sites selected, and the recruitment pathway, serve an ethnically diverse population reflected in the high percentage of ethnically-minoritised groups in services (3-9 times the national rate). The adaptation of HOP to Let's Talk included representation from people from a Black African background (7%), Black Caribbean background (7%), Asian background (12%) and White (74%), and for our feasibility trial, 40% of the participants identified as from a non-White ethnic background. We will seek representation from service users with experience of psychosis from ethnic backgrounds to form our Service User Reference Group (SURG) and seek advice on mapping out the local community organisations working with ethnic minority groups, including faith groups. The NIHR toolkit for increasing ethnically-minoritised participants in research highlights that trust is a common barrier to research and common trust related themes for minority ethnic groups include specific research practices. From month one, we will map out these community organisations and commence building relationships over the six-month set-up period. This will ensure feedback from these organisations on enhancing the trustworthiness of the research will feature in our study materials and staff training. Using site business intelligence data, the ethnicity of people with psychosis accessing services will be used to monitor that our eligibility criteria and referral pathways are not limiting inclusion. This will be monitored in our Trial Management Group (TMG), Trial Steering Committee (TSC) and Service User Reference Group (SURG). Where possible, a researcher from within an ethnic minority community that is representative of the geography of the site and incident rates of psychosis will conduct the assessments or deliver the intervention, which may help increase confidence in the study and reduce some barriers to participation such as trust in research.

7.10.2. Trial materials developed with inclusion in mind

To overcome any language barriers or lower levels of literacy we will produce participant information sheets in different formats, i.e., audio-visual an easy-to-read format with illustrations, and alternatives to written materials such as audio-consent.

7.10.3. Cultural sensitivity and competency training

All trial staff responsible for recruitment, retention, intervention delivery and other trial procedures will be provided with cultural competency training to enhance staff cultural sensitivity when engaging with referrers and service users/participants. This will also promote a clear message around equitable access to research opportunities for people from different ethnic groups, and for the trial to continually monitor for the potential impact of our recruitment pathways and materials. In addition to the above, we have reviewed the NIHR-INCLUDE guidance on barriers to participation in research for under-served group and we will endeavour to conduct assessments and intervention at a location preferred by participant. Our experience from our NIHR funded trials is that psychosis populations show a preference for home visits; we will conduct appointments in the participant's home when requested, subject any risk concerns that may contraindicate a home visit. This will remove physical barriers for attendance, may ameliorate additional carer time required to participate for those who are carers and parents, removes the risk of financial impact from travel costs and for any participants with health fears of hospitals i.e., from iatrogenic harm, being seen at home may present as a facilitator for engagement. Costs assigned for research worker travel to participant home can be repurposed to cover the cost of taxis for people with physical disabilities who are unable to use public transport and prefer an appointment at a community location.

7.10.4. Development work for a future trial of effectiveness with inclusion of non-English speaking participants

This study will include development work to enable the inclusion of non-English speaking participants in a future effectiveness trial. We will firstly map out who are the under-served groups from UK Ethnic Minorities with psychosis who are non-English speaking. This will be mapped out via: (a) access to, and regular review of business intelligence data at the delivery sites regarding ethnicity and languages spoken by the identified ethnic groups within the study population, and where possible within the limits of BI data this will also include requirements for interpreters this data will be reviewed by the Trial Management Group (TMG) through the duration of the study, (b) review and reporting of study referral and exclusions data to identify populations of people who have excluded on the basis of meeting the exclusion criterion non-English speaking and will include review of the languages spoken by those excluded from the study, which will be reviewed by the TMG, and (c) engagement with clinical services from whom we are recruiting to detail translation and interpreter requirements for the clinical population with whom they are working, this will include mapping the translation and interpretation costs for the intervention workbook and intervention delivery sessions at the sites. Our PPI team will carry out engagement and outreach work with community organisations who represent UK ethnic minorities who do not speak-English. This will also inform important cultural and intersectional stigma/ discrimination considerations required for non-English speaking participants. Where capacity and costs permit, we will carry out pilot work with non-English speaking service users with psychosis to inform learning for a future trial. The inclusive recruitment process will aim to appoint staff who speak multiple languages representative of the delivery site, which will facilitate pilot work with non-English speaking service users. Pilot work with non-English speaking service users will not contribute to the recruitment number at the site nor the research data for the intention to treat analysis; rather, pilot work will contribute to developing processes and tools for inclusion of non-English speaking participants in an effectiveness trial and completion of this work will be subject to staff capacity and costs within the existing research and treatment cost budget.

7.11. Proposed sample size

The between-group target difference at 4 months for the primary outcome QPR is set at 4.5 points; this is informed by work on the minimally important difference for this outcome (40). To detect this difference, assuming a standard deviation of 13.8 points and a conservative correlation between baseline and four months of 0.5 based on our feasibility work, we require outcome data on 306 participants randomised in a 1:1 ratio. We have inflated this to 352 participants based on 15% attrition.

Although the trial uses a partially nested design, there is a potential for a “therapist effect” in the intervention arm, we have assumed the intracluster correlation coefficient for PSW to be negligible. There are several reasons for this:

- Databases of therapist ICCS (51) state that therapist ICCs should be informed by designs, outcome, and therapist types like those of the trial being considered
- Previous trials of PSW (52) in an NHS setting assumed an ICC of 0.05, but found empirically there was no clustering on primary outcome (52), however, the primary outcome was binary and almost every participant experienced the outcome.
- We know from other databases of skilled-based intervention delivery that for continuous outcomes, ICCs are generally small (53).
- We will be monitoring closely fidelity to the HOP/ Let’s Talk intervention strategies and fidelity to peer principles through the lifetime of the trial and this will include monitoring for any PSW difference to implement corrective action in the form of training and that we have used this successfully on other NIHR trials (55-57).
- Baldwin et al. recommend when empirical or theoretical Indications are that an ICC is zero, to use a small but positive ICC., say 0.01 (51).

Keeping the sample size fixed, using the formulae in (54), we have above 85% power for ICC of 0.01 assuming 8 PSW with a mean caseload of 14.1 participants each. Our assumptions for the attrition and baseline-follow-up correlation are conservative for the four-month primary outcome time point. The analysis will account for PSW (see section 7.13).

Previous research from our group tells us we can expect indirect effects via individual mediators of between 30% to 50% of the total effect for effective interventions targeting known mediators. These expected proportions are consistent with estimates from the Let’s Talk pilot study. For a fixed sample size of 226 participants with outcome data on the primary outcome and mediator, 5% significance, and intervention effect on a single mediator of 0.4 to 0.5 standard deviations (this is conservative based on the Let’s Talk pilot study) a total effect of 0.375 (i.e. 4.5/12), we have 80% power (or more) to detect indirect effects of 35% or greater.

7.12. Recruitment Strategy

We will utilise multiple recruitment methods, successfully applied during our NIHR funded studies (55-57), to ensure maximum engagement of clinical services and outreach to all potentially eligible service-users. Data from Trust business intelligence show a potential pool of 19,766 individuals with a confirmed primary diagnosis of a schizophrenia spectrum disorder across the four sites. On average 41% of people with schizophrenia reported at least moderate levels of internalised stigma (15). This indicates is a pool of 8,104 eligible service users. Data from our feasibility trial shows a referral to randomisation ratio of 2:1 indicating at least 4,052 individuals who would meet criteria for the study and proceed to randomisation if approached about the study. The recruitment rates will be equal across sites with staggered recruitment in months 1-4 (2 per site m1; 3 per site m2; 4 per site m3 and m4) and then 5 participants per site/ month across a 19-month recruitment window. This staged approach will account for mitigating factors typically experienced in the setup of a clinical trial including contracting or governance delays, time to pilot and refine the screening approaches, establishing referral pathways, and trial promotion. We have identified four NHS sites that provide an experienced, clinically qualified Principal Investigator, who is employed by, or working very closely with, the relevant psychosis services from which we will recruit participants. This follows a key recommendation from our feasibility trial to ensure strong relationships with relevant referring services and facilitate referral routes. Knowledge of these services and existing relationships with the PI will maximise reach to service users via their healthcare workers (care coordinators, psychologists, psychiatrists). To ensure engagement of healthcare workers, who will be the first line in identifying service users for the study. We will hold stakeholder (healthcare workers) consultation in month 1 of the project and seek their perspective on the study, their guidance on referral processes that the least burdensome to staff and feedback on recruitment resources for healthcare workers. We will seek their guidance on preferred communication channels with the research team throughout the lifetime of the project. This will ensure healthcare workers' perspectives in the recruitment approach ahead of ethics submission in month 2-3. For the feasibility RCT we facilitated recruitment by providing information that increased healthcare worker confidence in identifying IS and disclosure distress, we will replicate that here. We will hold a recruitment launch for key stakeholders i.e., healthcare workers, voluntary organisations, service team leaders and NHS communications ahead of the recruitment window starting with key speakers from the field of psychosis and stigma research. This will raise awareness of the importance of addressing mental health stigma and discrimination and provide crucial information regarding the study referral processes. The project PPI lead will take a key role with the joint chief investigators (CI) in the design of the launch. We will signal the expertise within the trial by ensuring involvement from co-applicants who are experts in the field of psychosis, stigma research and PS. We aim to ensure that Research Ethics Committee, Health Research Authority and local NHS Capacity and Capability approvals are in place for this launch event to allow dissemination of the study recruitment materials.

We will recruit an experienced trial manager to monitor recruitment targets on a weekly basis and implement problem-solving solutions for issues by drawing on existing expertise within the team; the RAs will meet for group supervision to share best practice and learning from recruitment approaches across the sites. The local NIHR clinical research networks (CRN) have Research Delivery Teams (RDT) with robust links with local NHS services, and the research team has a strong history of successful collaboration with the networks to support recruitment to clinical trials. Where in place, we will use local NHS Standard Operating Procedures (SOPs) for delegation of screening and first contact from service staff to the RDT staff who are embedded within these clinical services. We will also utilise existing opt-in and/or opt-out methods for participant identification and recruitment, as approved by individual participating NHS Trusts. We will also accept referrals from research staff working on different research studies at all 4 recruiting sites who identifies a potential participant for Let's Talk 2. We will recruit from local voluntary/ third sector services to provide a self-referral route into the study. Potential participants may become aware of the study though a leaflet and poster in non-statutory/voluntary sector services/ waiting rooms of NHS services, via information about the study on our website www.psychosisresearch.com, or via the participating NHS Trusts' websites and/or social media accounts. Self-referrals are the method adopted by current RCTs of HOP in the USA and in Switzerland. A person making a self-referral will be informed on first contact that we will contact their care team to inform them of the self-referral (since being under the care of a secondary mental health service at one of the four study sites is an inclusion criterion) and seek verbal consent to do so. The study PPI co-applicants will lead liaison with the voluntary and third sector organisations during the study set-up period and ahead of the recruitment launch.

The approach throughout the recruitment phase will focus on continued awareness and engagement with relevant clinical services. We will achieve this by establishing regular contact between staff from the RDT, study RAs and services. Where possible, we will agree attendance at the service referral meetings and/or physically locate the RA at the service base. Continued presence and awareness of the study will ensure fair access to all potential participants throughout the lifetime of recruitment. Where agreements are not in place to regularly attend referral meetings, we will approach service staff to organise individual case load reviews to identify all eligible participants. As outlined above, we will provide all service users with psychosis at the delivery site the option to complete a stigma survey which will include basic eligibility screening items and an option for the service user to provide consent for a referral to the study to be made. This portfolio adopted survey will be delivered by RDN funded staff who have been provided with permission for screening and first contact from the clinical service team leaders. We will provide all relevant staff members with recruitment materials to outline the study. We will use strategies in previous NIHR funded trials to foster strong relationships with clinical teams including identifying service research champions and providing champion certifications, healthcare professional thank you cards, and updates regarding the trial progress. We will produce study merchandise (e.g., pens or post-it notes) which can be used by staff in services to ensure a continued presence. We will actively encourage feedback from potential participants who decline involvement in the study, record and evaluate all reasons for decline (where obtained) and share these with our PPI group to determine adaptations to our recruitment approach.

7.13. Statistical Analysis

We will report participant flow using the CONSORT 2018 extension for social and psychological intervention trials (58). Baseline characteristics, follow-up measurements and safety data will be described using appropriate descriptive summary measures. The primary outcome will be analysed using a repeated measures mixed effect model accounting for baseline score, design covariates, nominal time, and treatment-by-time interaction, with participant and PSWs as random effects accounting for potential clustering in the PSW arm a using heteroscedastic partially nested mixed-effects (59). The treatment policy estimand will be estimated as the adjusted between group mean difference from the model for each time point separately. Missing data will be handled using multiple imputation (assuming data are missing at random) and sensitivity analyses based on pattern-mixture models. Full methodological details will be pre-specified in the Statistical Analysis Plan. Secondary outcomes will be analysed using similar strategy with models suitable for the outcome (i.e., logistic regression for dichotomous outcomes). All treatment effects will be derived from these models and presented with 95% confidence intervals. There will be no interim analysis. To test treatment-effect mechanisms, mediation analysis will use parametric regression models to estimate the indirect effects of Let's Talk on the mechanism measures on primary outcome. Results will be reported using the AGrEMA guidelines (60).

7.14. Planned interventions

The two parallel arms of this trial are a peer-delivered intervention (Let's Talk) + TAU (treatment condition) vs. TAU alone (control condition).

7.14.1. Treatment condition (Let's Talk + TAU)

The proposed study will employ the treatment manual and workbook devised and refined during our feasibility study, which grounds the intervention in the principles of peer support (20). The workbook has discrete modules outlined in Table 2. 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 videocall or telephone as a contingency. Qualitative data from the Let's Talk feasibility trial indicated that to improve acceptability, the window for delivery of the intervention should be extended. The role and function of extending the window is threefold: (1) to allow sufficient time to cover the intervention strategies, (2) to build the peer relationship, and (3) to manage endings. Adherence checklists and electronic session records will be used to maximize fidelity to the manual, with any protocol divergences monitored during PSWs supervision. Important treatment milestones will likewise be assessed and monitored, and intervention sessions will be audio recorded for the purpose of fidelity to the intervention manual checks. Adherence will be defined as having received at least 4 sessions.

Table 2: Let's Talk Workbook modules

Module #	Details
Module 1	Getting to know each other: (1) expectations of the intervention, (2) what is peer support, (3) getting to know each other's hobbies/ interests, values, and important relationships, (4) getting to know each other regarding mental health and psychosis experiences, and preferred terms for mental health experiences.
Module 2	Talking about mental health: (1) negative and positive terms about mental health and psychosis, (2) hurtful (stigmatising) and helpful words about psychosis, (3) finding out facts to challenge stigma including myths vs. facts about psychosis with links to recovery stories and normalising information in the workbook appendix.
Module 3	Hurtful and helpful self-talk about mental health experiences: (1) sharing hurtful and helpful self-talk understanding & experiences, (2) analysing a story for hurtful and helpful self-talk, and (3) five steps for changing personally hurtful self-talk.
Module 4	Disclosure options: (1) reasons people choose to disclose, (2) benefits and costs of disclosure, (3) short-term and long-term costs and benefits of disclosure, (4) Five points to remember about disclosure decisions, and (5) my benefits and costs analysis.
Module 5	Choices and settings for disclosure: (1) six approaches to talking about mental health, (2) benefits and costs of the six approaches including examples and own benefit and cost analysis, (3) Who is a good person to disclose to? Evaluating types of disclosure relationships and evaluating the water for a good person to disclose to.
Module 6	How others may react to your disclosure: (1) evaluating helpful and unhelpful reactions, (2) evaluating experiences after an unhelpful reaction including an option to role play an unhelpful reaction, and (3) ways to prepare or manage an unhelpful reaction.

Module 7	Sharing information about your mental health experience: (1) different ways to share your mental health experiences, (2) Creating your own approach to sharing your experiences of mental health and psychosis, (3) a structured guide to setting up your own narrative about your mental health and psychosis experiences, and (4) practicing sharing your experiences.
Module 8	Moving forward: (1) Evaluating your experience of disclosure, (2) insights about the intervention and future directions and (3) where to go to find further peer support and connection.
Appendix	National and local organisations that can provide mental health support; Example costs and benefits of disclosing; Example costs and benefits of disclosure by social media; Examples of characteristics and qualities of people and relationships for talking about mental health; Recovery stories and resources about psychosis/; Local peer support groups; signposting regarding protection again unwanted disclosures and legal rights regarding disclosure; Disclosure narrative example.

Peer Principles for Let’s Talk delivery: A set of operational principles derived through a systematic review of the literature on individually delivered PS and a review of principles by a UK National Expert panel of people sharing, leading or researching PS has been developed to guide the delivery of PS in mental health services (20). We will adopt these principles (20) for the delivery of Let’s Talk, as a named collaborator Gillard, lead researcher in development of these principles will provide training and oversight of fidelity to these principles: (1) support the building of safe, trusting relationships based on shared lived experience, (2) ensure that the values of mutuality and reciprocity underpin the peer relationship, (3) promote the validation and application of experiential knowledge in the delivery of PS, (4) enable peers to exercise leadership, choice and control over the way in which PS is given and received, and (5) empower peers to discover and make use of their own strengths and build and strengthen connections to their peers and wider communities.

Participant and PSW safety and wellbeing are paramount. For the feasibility RCT we established several methods to ensure both participant and PSW safety and wellbeing, which we replicated here. PSWs are NHS employed (substantive or honorary contracts) and will complete all NHS mandatory training, including safeguarding vulnerable adults and children and clinical risk management, and work within NHS policy. The job person specification requires at least a Level 2 approved peer mentor course or equivalent training/ experience, and at least one year’s experience in a peer researcher or PSW role. Our strategies ensure a high degree of competency in the role before commencing in post. All PSWs will receive a month’s training covering the intervention manual, role play practice and fidelity checks, participant engagement approaches, supervision structures and support, competency in clinical risk assessment (at the level appropriate for their role) and steps for risk and safeguarding escalation. Training will include sessions with a HOP specialist and psychologist (named collaborator Larson), Peer Specialist (Pilling) with experience of delivering and supervising PSW and clinical supervisors. Training will include distress management, as outlined above in section 5.6. We will use supervision structures tested in the feasibility RCT including PSW supervision to support their own personal wellbeing and weekly group supervision with a peer specialist and co-investigator that provides a shared space to connect with their fellow PSW, offer mutual and reciprocal support, share best practice, and celebrate success and seek support for delivery queries. For the feasibility RCT there were no adverse or serious adverse events determined to be related to the intervention. All four PSWs remained in post for their contractual period, which indicates the success of our procedures in ensuring their wellbeing. For our NIHR funded RAPID Trial (NIHR132690), for people with a serious mental health condition who have experienced a recent suicidal crisis, one intervention arm is remotely delivered PS and to date there are no adverse or serious adverse events determined to be related to the intervention.

7.14.2. Control condition (TAU alone)

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, including access to peer support as part of TAU, will be monitored via screening participants’ electronic patient records after the final assessment using a treatment as usual case report form. Except for emergent risk issues, TAU alone will also not involve liaison between researchers and the participants’ healthcare teams.

7.15. Proposed outcome measures

Efficacy outcomes will assess overall personal recovery and with additional clinically relevant outcomes of targeted psychiatric symptoms (depression, social interaction anxiety, hallucinations and unusual beliefs) and quality of life. All measures will be collected at baseline, 4-months and 12-months.

7.15.1. Primary outcome

The primary outcome will be the total score on the 15-item QPR (37) at 4 months. 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 (9) and the QPR has been cited (61) as the only measure of recovery that directly maps onto all 5 processes of the influential CHIME framework of personal recovery (4).

7.15.2. Secondary outcomes

Secondary outcomes will assess relevant dimensions of psychiatric distress and quality of life.

1. The Social Interaction Anxiety Scale (62), 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 has been shown to be 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) (44), 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, fourth edition) criteria. It classifies current symptoms on a scale of 0 (not at all) to 3 (nearly every day).
3. DIALOG (43) a validated, 11-item, patient reported outcome and experience measure (PROM/PREM), which 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 revised Green et al. Paranoid Thoughts Scale a validated 18-item, patient reported outcome of paranoia comprising two subscales to assess ideas of reference and ideas of persecution. (63)
5. The Psychotic Symptoms Rating Scale: Multimodal Hallucinations, an unpublished scale adapted from PSYRATS-AH (64) for assessing the presence and impact of non-auditory hallucinations.

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 (42).
2. Stigma stress will be assessed by the 8-item Stigma Stress Scale (65).
3. Single item disclosure distress scale (41).

For details of assessment of safety see section 11.2.

7.15.3. Assessment and follow up

Assessors blind to allocation will conduct assessments at baseline, 4-month follow-up (end of treatment) and 12-month follow-up (post randomisation). Blinding of the allocation code of a participant will be maintained for Research Assistants (Ras) until all outcomes for that participant have been collected, scored and both scoring and data entry queries resolved. We will collect demographic information at baseline and a reduced demographic form at follow up to track potential change in education, employment, training, and living arrangements.

Adverse events and intervention related adverse effects will be monitored though the following methods: (1) these events are likely to come to the attention of the PSWs or assessors and will be reported to the trial manager and CI on identification, (2) we will also check medical records at trial exit for serious adverse events for each participant.

7.16. Proposed deliverables

Several outputs are expected from the research. The trial is designed to answer clinically significant hypotheses using the fewest number of participants, thereby maximising the use of resources and value for money. It will generate evidence for the clinical efficacy of a peer-led intervention, deliverable within the NHS that is intended to reduce the impact of stigma on the personal recovery of people with experience of psychosis. We will produce an updated intervention protocol, workbook, plus associated training materials, which will help facilitate effective implementation and sustainability within the NHS if effectiveness is proven in a future trial. These will be made publicly available, free of charge once the research is published. This output will address a number of unmet needs including improving the efficacy of PS and responding to the NHS Taskforces expansion of paid PSW roles in the NHS in their vision for mental health services (13).

Several high-quality peer-reviewed open access publications are expected from the body of research. A core component of this research is the training and skilling-up of the PSWs involved in the research through our training package. We will generate quantitative data that may be of interest to researchers examining both the efficacy of the HOP intervention, PS, and stigma-focused interventions, e.g. for systematic review and meta-analyses, individual patient data analysis. The database will be made freely available to researchers upon reasonable request. Furthermore, the study will also provide data on the hypothesised treatment mechanisms for Let’s Talk, thereby offering potential improvements and refinements for future interventions which target internalised stigma.

Impact from this research will be achieved in several ways. This research will provide an effective PS intervention to help people experiencing internalised stigma and psychosis, which are both causes of disability and mortality. It will provide a manualised PSW intervention and training materials, which will facilitate effective uptake, implementation, and sustainability in the NHS if effectiveness if proven in a future trial. The intervention will provide PSWs with role clarity, increased job satisfaction and increase retention rates. Our focus on psychosis is clearly consistent with NHS priorities and needs, since it is associated with significant personal, social, and economic costs, and psychotic disorders account for a large proportion of the national health and social care budget.

7.17. Value for money

Careful attention has been paid in producing the costs to ensure value for money including costing and employment of the RAs through the NHS, which offers value for money and employment of the second RA post will be only during the busiest period of recruitment and follow-up (m6-m26) to ensure sustained recruitment and retention rates. The training protocols and resources for training established in the feasibility trial will ensure a short-time frame (one month) from staff appointment to completed training ahead of recruitment commencing. We have, on the advice of the NIHR EME Stage One panel extended our set-up phase by two months (6 months total), this set-up time provides best value for money balancing sufficient time for contracting, governance approvals and CTU database set-up whilst maximising the PI (Pyle)’s extensive experience of Trial Management and study set-up across three completed NIHR funded trials (55-57), an active NIHR funded large-scale multi-arm, multi-stage (MAMS) trial (NIHR132690) and the completed Let’s Talk feasibility RCT (NIHR200460). As outlined below in section 7 we will commence several tasks before the start of funding, a strategy we have demonstrated with success on our other NIHR funded trials; the infrastructure for Pyle, Morrison and Byrne at The Psychosis Research Unit facilitates this work. We have included in the design an internal pilot to ensure demonstrated ability to initiate all sites on time, recruit and retain the required number of participants for the study; we are confident progression to full trial will be achieved but inclusion of an internal pilot safeguards against unnecessary loss of financial investment in the highly unlikely circumstances that our internal pilot criteria are not met. Psychosis accounts for a large proportion of the NHS and social care budget with total monetary costs estimated as £11.8 billion per year (64). There is a continued need to reduce the economic, social and personal burden associated with psychosis (24). Developing evidence-based interventions to support this population in personal recovery may contribute to significant savings for the health and social care budget and is consistent with current principles in treatment guidelines. If the intervention is found to be effective, this could have implications for the clinical commissioning of local mental health services, and for the development of national guidelines for the provision of care for patients with psychosis. Likewise, there is also potential for immediate impact on ~176 NHS patients who are allocated to receive the Let’s Talk intervention.

8. Dissemination, Outputs, and anticipated impact

The proposed study will provide evidence regarding clinical efficacy of a novel, peer-led intervention that targets the harmful effects of stigma (internalised stigma; stigma stress and reduced empowerment) in a psychosis population within the NHS. This output will address several unmet needs, including improving the efficacy and accessibility of evidence-based psychosocial, peer-delivered interventions for adults with psychosis, developing the PS workforce, and responding to the NHS’s Long-Term Plan for PSW as part of mental health workforce provision. In addition to several high-quality peer-reviewed publications (including the trial protocol and analysis of primary and secondary measures), a core component of this project is the training and skilling-up of the workforce involved in the research. In this respect, intervention manuals will be made freely available via a web portal for PSW to utilise which will facilitate effective uptake, sustainability, and implementation within the NHS if effectiveness is proven in a future trial. This will be supported through our existing links with the Innovation and IP Management Services within the host site, with no intellectual property barriers expected. We will further generate quantitative data that may be of interest to researchers examining the efficacy of psychosocial interventions (e.g., for systematic review, meta-analyses, and individual patient data analysis), including the impact of targeting key stigma related variables to promote personal recovery. The fact that NHS PSW will deliver the treatment should help to immediately disseminate the approach if effectiveness if proven in a future trial. In this regard, our pilot trial confirmed that PSW already experienced in working in NHS services were able to deliver the intervention without time-intensive training, which has positive implications for scalability. We will utilise dissemination strategies including workshops and conference presentations delivered to a diverse range of audiences (i.e., service-users, healthcare professionals, academics). We will continue to embed the perspectives of people with psychosis in sharing the results, including presentations delivered by team members with experience of psychosis, engaging with voluntary sector organisations and community groups with whom we have built links throughout the trial such as MIND. We have included costs for our Lived Experience Advisory Forum (LEAF) to contribute to the dissemination plans and participant summaries in year 4.

9. Project/ research timetable

Prior to the start of the study: work will commence to prepare the paperwork required for ethics, HRA and NHS Capacity and Capability (C&C) approvals, which will include strong communication with the Research and Development (R&D) departments at each of the four sites. Each site will commence engagement with senior managers, clinicians and service users in the services participating in the study to raise awareness of the study before recruitment commences and to ensure sign off from senior managers. Pyle and Morrison will consult closely with the sponsor and sites to ensure timely initiation and ratification of the collaborator agreement. Pyle and site leads will commence liaison with the NHS Trusts to identify existing peer members of staff who have substantive contracts and can take on the role as a personal development opportunity. All sites have established PSW roles. Each site will identify members of the Lived Experience Advisory Forum (LEAF) made up of 4-5 service users/ patients from the site with experience of psychosis.

Months 1-6 (study set-up and training):

LEAF will meet to support the development of the study materials, including short film/ animation script, ahead of ethics submission and support community network mapping (m1). Healthcare professional stakeholder meetings to review information provision required for recruitment and referral pathway preferences (m1-2); CTU database (m1-6); staff recruitment (m2-5); finalise training materials for PSW and RAs established in the feasibility RCT including LEAF in m3 to consult regarding staff training (m1-5); community organisation mapping and outreach (m1-6); harmonise the intervention for our context and finalise the intervention manual and schedule for fidelity checks during the trial (m1-5); ethics, HRA, local NHS Capacity and Capability approvals, NIHR portfolio adoption, ISRCTN registration (m3-6); staff training including LEAF members to support training the RA (assessment role play + feedback) (m6); established TSC and DMC with first meeting in m6; study launch event (m6).

Months 7- 37: Efficacy Trial: internal pilot as outlined in section 5.1 (m7-16; total sample size for internal pilot n=172; Month 17: internal pilot progression criteria review; full scale trial recruitment (m17-25; 4/site/month; total recruitment for full scale trial n=180; sample size by end of m25 =352; intervention delivery for the internal pilot and full trial (m7 -31 accounting for final booster sessions); end treatment assessments (m7-m29) 12 month follow-up assessments (m19-37); data cleaning using strategies employed on previous trials of commencing cleaning as time point's end, analysis, site closure and report writing and participant summaries. A summary of the project plan can be seen in Appendix 1. Each site's LEAF will meet twice in year 2 and support RA training for the second cohort of RAs in year 2. LEAFs will meet once in years 3 and 4.

10. Project management

The trial will be supported by CHaRT who will provide independent randomisation and databases. Statistical support will follow CHaRT Standard Operating Procedures. Greater Manchester Mental Health Foundation Trust will be the primary sponsor. In accordance with high standards of research governance we would ensure researchers receive training in the International Conference on Harmonisation (ICH) Guidelines - Good Clinical Practice before recruitment commences. We will set up a Trial Steering Committee (TSC) and a Data Monitoring and Ethics Committee (DMC) prior to the start of the study. The TSC will comprise representatives from the research team, independent clinicians and statistician, a representative of the funder will be invited, and a service user, and will have an independent chair. It will meet annually and initially before the trial begins for approval of the protocol and standard operating procedures. The TSC will monitor and supervise progress, consider reports, and make recommendations. A DMC will be established to monitor (1) recruitment of study participants, (2) ethical issues of consent, (3) quality of data (including missing data), (4) internal pilot results (5) the incidence of adverse events, and (6) any other factors that might compromise the progress and satisfactory completion of the trial. This will have an independent chair and include an independent statistician and clinician. It will meet on a 6-monthly basis. Communication within and between sites: Each site will have a weekly team meeting to ensure regular communication and interaction between site leads, PSWs and research assistants (measures will be followed to avoid blind breaks). There will be monthly Trial Management Group with all applicants via video conference. The Trial Manager will conduct weekly telephone supervision with all RAs that will focus on assessor reliability of the interview measure, recruitment, liaison with referrers, compliance to follow-ups, and specific scoring queries. In addition, they will chair group RA supervision regarding recruitment and engagement to share best practice. The PSWs will receive weekly group supervision and local supervision from a clinician. Local clinical supervision will focus on problem solving, personal wellbeing and risk management. PSW will meet with Pyle every month to focus on fidelity and adherence to the manual.

11. Ethics/ regulatory approvals

National Research Ethics Committee and HRA approval will be obtained prior to the start of data collection. Only those who agree to provide written informed consent will be included in the study. Potential participants will receive a PIS that includes a contact number for the study team. The investigator will permit study related monitoring, audits, Health Research Authority review and regulatory inspection providing direct access to source data/ documents

11.1. Risks and anticipated benefits for trial participants

This study will add to the evidence base for the range of psychosocial interventions that should be provided to improve personal recovery outcomes for people with psychosis, who remain among the most socially, excluded groups in society. If our intervention were found to be significantly superior to TAU in improving personal recovery this could have implications for the future evidence-based management of similar patients within secondary care mental health services. A potential risk is that some participants might find the research assessment process distressing. Participants will be offered choice regarding the timing, modality (remote or face-to-face) and length of the assessments, including the option of breaks and assessments spread across multiple occasions (to minimise burden at any one time). We have a standardised protocol for managing distress (outlined above in section 7.7), which has been developed with service users. The research assistant will gain advice from their supervisor and take any appropriate action to minimise the participant's distress.

The participant will be able to freely withdraw from the study at any point, which will not affect their statutory care.

11.2. Assessment of safety

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject to whom a medicinal product/device/intervention has been administered, including occurrences which are not necessarily caused by or related to the latter. This may include incidents of self-harm. A Serious Adverse Event (SAE) will be defined as an adverse event that: results in death; is life-threatening; requires hospitalisation or prolongation of an existing hospitalisation; results in persistent or significant disability or incapacity; consists of a congenital anomaly or birth defect; Other important medical event if determined to be serious based on medical judgement. Foreseeable adverse events include psychiatric hospital admissions, self-injury and/or suicidal ideation with a behavioural component. Analysis of the feasibility trial data indicates these were commonly occurring adverse events within the study population. The response to an adverse event will be determined on a case-by-case basis and in line with Health Research Authority (HRA) guidance. SAEs will be reported to the main REC when in the opinion of the CI(s) is the event was: related (that is, it resulted from administration of any of the research procedures, and unexpected (that is, the type of event is not listed in the protocol as an expected occurrence). To ensure independent scrutiny of SAEs, the DMC will monitor their occurrence for any patterns. We will adhere to the sponsor's Standard Operating Procedures for Recording and Reporting of adverse events for GMMH sponsored studies (RDSOP41). However, prior to receiving ethical and regulatory approvals, the sponsor agreed that SAEs may be reported within five working days of the CI becoming aware of them (rather than 24 hours, as is usually the case for GMMH-sponsored studies under RDSOP41). The rationale for the extended reported timeline discussed with the sponsor is firstly that Let's Talk 2 is considered to have a low risk profile, being a non-CTIMP (Clinical Trial of an Investigational Medicinal Product) study, and the feasibility trial Let's Talk having a low SAE rate. Secondly, the extended reporting timeline will allow sufficiently thorough information-gathering and discussion to decide upon severity, relatedness and expectedness of SAEs that arise.

11.3. Obtaining informed consent

Written informed consent will be obtained from each participant prior to their inclusion in this study in line with the Information Sheets and Consent Forms, Guidance for Researchers and Reviewers, Version 3.2 May 2007 (National Research Ethics Service: NRES). Participants will be given least 24 hours to consider the information before providing written informed consent. In the event of it being unfeasible to seek written informed consent (e.g. in the instance of future pandemics or national crises as with covid-19) consent will be taken remotely via telephone or MS Teams and the consent appointment audio recorded. In the instance that consent is taken remotely we shall adhere to the following approach, which has been used for our other NIHR funded trials (RAPID; Let's Talk; Talking With Voices II):

1. The consent visit will be audio recorded as evidence of the informed consent visit and the participants consent to the study. The participant information sheet outlines that in the case of remote consent we will require an audio recording of the participants consent.
2. The participant will be asked to state their name in full and the date.
3. The research assistant shall read out each statement in full and ask the participant to confirm if they agree with the statement. The research assistant shall then initial each statement box on behalf of the potential participant to document participant agreement.
4. The research assistant shall sign and date the consent form.
5. Where possible, the research assistant shall seek a written signature from the participant later.

11.4. Data collection, management and anonymity

Each study participant will be assigned a unique trial identification number at the start of the assessmentocess. This number will be written on all clinical assessment forms, datasheets and databases used to record information on our study participants to ensure pseudo anonymity. A registration record linking patient identity and trial ID number will be kept electronically at each site on a secure NHS or University drive, password protected and only accessible to members of the research team as per the study delegation log.

Pseudonymised research data will be entered into the CHaRT Clinical Trials Unit, electronic data entry database.

11.5. Quality assurance

11.5.1 Clinical Trials Unit

The trial will be run under the auspices of the Centre for Healthcare Randomised Trials (CHaRT), a fully registered UK Clinical Research Collaboration Clinical Trials Unit. CHaRT has internationally recognised expertise in the design, conduct, analysis and reporting of multicentre trials. CHaRT has been fully engaged with the co-Chief Investigators throughout the planning stage to ensure the optimal scientific design, with the best and most appropriate analysis and suitable methods of managing and conducting the trial. The programmer will create, maintain and update all applications including the randomisation system and all electronic database system. The statistician will take responsibility for all aspects of the statistical analysis. This specification fits in with the CHaRT resource model and will adequately support the trial's statistical needs (including the specification of the randomisation system, liaison with the database managers and IT programming of the study databases, preparation of the trial Statistical Analysis Plan, creation and delivery of progress reports to the independent Data Monitoring Committee, assist in enhancing the quality of the trial data by statistical input to remote central monitoring of accumulating data, and finally the running of all the statistical analyses for the final data set).

Randomisation will be undertaken by recruiting site staff, by authorised staff onto the randomisation system. Pseudonymised research data will be entered in the CHaRT electronic database system, we will not enter any personal data into the CHaRT database that can identify a person i.e., we will enter no names, no contact details, no date of birth, no medical record IDs and no participant initials. Access will be provided to authorised staff. A full audit trail of data entry will be automatically date and time stamped, alongside information about the user making the entry within the system. System access will be strictly restricted through user-specific passwords to the authorised research team members. No data will be entered onto the randomisation system unless a participant has signed a consent form to participate in the trial. The co-Chief Investigators team will undertake appropriate reviews of the entered data, in consultation with the project analyst, for the purpose of data cleaning.

11.5.2 Monitoring

Data accuracy checks and day-to-day requirements around monitoring will be delegated from by the sponsor to the trial team including central and remote monitoring of sites. Quality checks will be made by the trial management team. Checks will be made on consent forms, participant outcome measures, and data entry. These checks will include accuracy of completion of consent forms in line with GCP, clear and concise labelling of participant outcome measures, correction of errors in line with GCP, completeness of assessment packs, storage in line with ethical approval, and timely data entry. Site audits will be conducted by the trial management time.

Eligibility sign-off before randomisation will be carried out by a member of the management team with delegated responsibility. The member of the management team will review eligibility with the research assistant and will be responsible for signing the eligibility checklist.

11.6. Serious breaches

We will record and report to the study sponsor all protocol and GCP breaches in line with the sponsor's Standard Operating Procedure for Notification of a Serious Breach of GCP or the Clinical Trial Protocol (RDSO09). All trial staff will be trained to follow RDSOP09 to ensure clear and transparent reporting of either GCP breaches or protocol deviations.

12. Project/ research expertise

The Psychosis Research Unit (PRU), the Institute for Psychiatry, Psychology and Neuroscience – Kings College London, and The Consortium for Stigma and Empowerment are world-leading research units and organisations with an extensive history of successful multi-site NIHR-funded RCTs for developing and evaluating psychological therapies for psychosis and stigma research. Collectively, the research team has expertise and widespread experience in 1) treatment of psychosis; maintenance factors associated with psychosis; stigma and discrimination research; stigma intervention development; 2) CI and PI roles; trial management; training/supervising staff in the context of psychosis interventions; 3) LEx, PPI, and PSW expertise including PSW training; 4) trial methodology and statistical analysis; 5) disseminating evidence-based therapies; ensuring adherence and competence in delivery of therapies and PS work; 6) NHS management and implementation. Three UK RCTs of a psychosocial intervention to target internalised stigma for people with psychosis have been conducted by our research group; two trials of Cognitive Behaviour Therapy (67, 68) and one feasibility Randomised Controlled Trial (RCT) of PS intervention called 'Let's Talk', funded through the National Institute for Health Research (NIHR) Research for Patient Benefit programme (NIHR:200460; ISRCTN17197043) and completed on 15/09/2023.

13. Success criteria and barriers to proposed work

Our primary measurements of success are provided in our progression criteria table. Delays in REC, HRA and local NHS governance approvals are a potential risk given these approvals must be in place for each phase of the programme to commence. We will begin governance approvals for REC, HRA and NHS Trusts on hearing confirmation of funding i.e. during the pre-study phase. Oversight of governance approvals will be provided by MP who is an experienced Trial Manager for NIHR funded trials (ACTION; FOCUS; MAPS; RAPID) each of which has commenced on time. It is possible that we will experience staff turnover (PSWs, and RAs), which could be a risk to delivery of the intervention and assessment of research participants. We have experience of staff turnover from previous NIHR funded trials and have experience of utilising local resources to provide interim support for recruitment and assessment. However, for the Let's Talk feasibility RCT we retained our PSW workforce for the full duration of their contracts. We will have training packages that can be delivered remotely (if necessary) to ensure we can swiftly train new RAs (thus limiting any impact on recruitment or follow-up). Recruitment to target is a potential risk. However, data from business intelligence at the sites suggests a potential pool of approximately 8,104 individuals with psychosis who receive care from the NHS site, giving a potential total participant pool of [x]; Additionally, all site leads have strong clinical links with relevant services for people with psychosis and all sites have extensive experience of liaison with clinical teams, the use of launch events for awareness raising, and liaison with voluntary sector organisations. Trial management will be led and supervised by MP who has extensive experience in problem solving recruitment and retention issues and ensuring delivery of projects to time and target. We have had considerable past success with recruitment of people with experience of psychosis and/or schizophrenia spectrum diagnoses as demonstrated by our strong history of recruiting to psychosis trials. The local RDTs research networks have robust links with local services, and all site leads have a strong history of successful collaboration with the networks to support recruitment to clinical trials. Risk of attrition could jeopardise the success of the internal pilot and the integrity of the definitive trial. Our sample size calculation would allow for a dropout rate of 15%. However, this is a conservative estimate of drop-out. In our existing NIHR funded studies, dropout rates have been low (Let's Talk feasibility RCT withdrawal rate 7%) We will use evidence based strategies to maximise retention and minimise loss to follow up (such as assertive outreach approach to assessments; high quality training for RA, inclusion of crisis card provision and signposting in the assessment sessions) (65). Risk of bias could jeopardise the integrity of the trial; however, our primary outcome is objective, and we will reduce the risk of bias by keeping assessors blind to allocation. Blindness will be maintained using a wide range of measures, such as separate offices for the APs/PSWs and research assistants, protocols for answering telephones, message taking and secretarial support, separate diaries and pigeonholes and data file security, using passwords and encryption of randomisation information. These procedures have been successful in our previous trials. Both DMC and TSC will regularly monitor unblinding by each centre and implement corrective action if necessary. Any accidental unblinding will be recorded and subject to participant distress and engagement we will reallocate the remaining assessments to a researcher who remains blind.

14. End of Study

The end of recruitment will be 31st May 2027. The last visit for follow-up will be 31st May 2028. The end of trial is defined by completion of data analysis and the final funder report submitted, which will be 31st August 2028.

15. Finance and Insurance

This study is funded by the National Institute for Health and Care Research (NIHR) via The Efficacy and Mechanism Evaluation (EME) programme and is sponsored by Greater Manchester Mental Health NHS Foundation Trust. Insurance and indemnity are provided via the sponsor.

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Year 1	**M1 May’25**	**M2 Jun’25**	**M3 Jul’25**	**M4 Aug’25**	**M5 Sep’25**	**M6 Oct’25**	**M7 Nov’25**	**M8 Dec’26**	**M9 Jan’26**	**M10 Feb’26**	**M11 Mar’26**	**M12 Apr’26**
Finalisation of approvals (REC/HRA, NHS); staff recruitment	🟦	🟦	🟦	🟦	🟦	🟦						
Finalise treatment manuals	🟦	🟦	🟦	🟦	🟦	🟦						
Systems (randomisation/ database, website)	🟦	🟦	🟦	🟦	🟦	🟦						
Staff training						🟦						
Site initiation meetings and study launch						🟦						
Internal pilot recruitment (n =172)							🟦	🟦	🟦	🟦	🟦	🟦
Intervention delivery							🟦	🟦	🟦	🟦	🟦	🟦
4-month assessments											🟦	🟦
Year 2	**M13 May’26**	**M14 Jun’26**	**M15 Jul’26**	**M16 Aug’26**	**M17 Sep’26**	**M18 Oct’26**	**M19 Nov’26**	**M20 Dec’27**	**M21 Jan’27**	**M22 Feb’27**	**M23 Mar’27**	**M24 Apr’27**
Internal pilot recruitment (n =172)	🟦	🟦	🟦	🟦								
Progression criteria data report preparation and review					🟦							
Full trial recruitment (n=180)					🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
Intervention delivery	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
4-month assessments	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
12-month assessments							🟦	🟦	🟦	🟦	🟦	🟦
Year 3	**M25 May’27**	**M26 Jun’27**	**M27 Jul’27**	**M28 Aug’27**	**M29 Sep’27**	**M30 Oct’27**	**M31 Nov’27**	**M32 Dec’28**	**M33 Jan’28**	**M34 Feb’28**	**M35 Mar’28**	**M36 Apr’28**
Full trial recruitment (n=180)	🟦											
Data clean and lock for baseline		🟦										
Intervention delivery	🟦	🟦	🟦	🟦	🟦	🟦 booster						
4-month assessments	🟦	🟦	🟦	🟦	🟦							
Data clean and lock for 4-m assessments & intervention data						🟦		🟦				
12-month assessments	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
Year 4	**M37 May’28**	**M38 Jun’28**	**M39 Jul’28**	**M40 Aug’28**								
12-month assessments	🟦											
12m data cleaning, analysis, report, pp easy read summaries	🟦	🟦	🟦	🟦								