

A peer-delivered intervention to reduce the impact of psychosis stigma and discrimination: a feasibility Randomised Controlled Trial

## Statistical Analysis Plan

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## Signatures

By signing this document, I am confirming that I have read, understood and approve the statistical analysis plan (SAP) for the Let's Talk trial.

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## Version History

SAP version	Protocol version*	Section number changed	Description of and reason for change	Date of change
Version 1	Version 5		New document, based on SAP template Version 2	

\* Please refer to 'Statistical Analysis Plan (SAP) review after Protocol updates' document that will be updated throughout the trial, documenting any amendments to the protocol and its relevance to the SAP.

## Glossary of Abbreviations

*Table containing all abbreviations used in the statistical analysis plan, e.g.*

AE	Adverse Event
CHaRT	Centre for Healthcare Randomised Trials
CDS	The Calgary Depression Rating Scale for Schizophrenia
CI	Confidence Interval
CRN	Clinical Research Unit
CONSORT	Consolidated Standards of Reporting Trials
DDS	Disclosure Stress Scale
DMC	Data Monitoring Committee
EQ-5D-5L	EuroQol Group's 5-dimension health status questionnaire 5 level
HOP	Honest Open and Proud
HSRU	Health Services Research Unit
IS	Internalised Stigma
ISS	Internalised Shame Scale
ITT	Intention-to-Treat
MANSA	Manchester Short Assessment of Quality of Life Scale
PMG	Project Management Group
PROMS	Patient Reported Outcome Measures
PS	Peer Support
QPR	The Process of Recovery Questionnaire

RCT	Randomised Controlled Trial
RES	Rogers Empowerment Scale
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SERS	Self-Esteem Rating Scale
SIAS	Social Interaction Anxiety Scale
SIMS	Semi-structured Interview Measure for Stigma in Psychosis
TAU	Treatment As Usual

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# Let's Talk: a feasibility Randomised Controlled Trial

## 1. Introduction

This statistical analysis plan (SAP) documents the analysis for the Let's Talk trial. The SAP is based on the protocol version 5 and any deviations from the plan will be described.

Stigma, defined as “an attribute that is deeply discrediting” which turns a person from “a whole and usual person to a tainted, discounted one”<sup>1</sup> and a consequence of this is internalised stigma (IS), which is internalisation of stigmatising beliefs towards oneself. Peer support (PS) is an approach to address IS which has shown promise<sup>2</sup>. The Schizophrenia Commission identified that service users with psychosis and schizophrenia value PS and recognised that interventions such as PS can address stigma and discrimination.

Honest Open and Proud (HOP) programme, which is a peer-led approach, provides an opportunity for patients to discuss mental health stigma and explore their disclosure decisions with peers has shown promise. This has recently been modified and changed to Let's Talk through review of the workbook, manual and through Public and Patient Involvement. Three pilot randomised controlled trials (RCTs)<sup>3-5</sup> have looked at the efficacy of Let's Talk but none of these have been conducted in the UK or with those experiencing psychosis.

## 2. Study Aims and Objectives

The principal objective is to evaluate the feasibility and acceptability of conducting a RCT of the 'Let's Talk' per-delivered intervention with people who experience psychosis.

The specific objectives of the trial are to assess:

1. The proportion of eligible people clinicians are willing to refer, the proportion of eligible people willing to participate, the proportion of participants who engage with the intervention



2. The proportion of participants who select in-person vs. remote delivery of the Let's Talk peer-delivered intervention.
3. The drop-out rate.
4. The characteristics of trial participants to refine selection criteria.
5. The appropriateness and integrity of Let's Talk workbook and manual.
6. The feasibility and acceptability of the intervention to participants.
7. The randomisation procedures.
8. The relevance (to participants) and validity of the measures to assess effectiveness, service use, health status, safety and acceptability in a subsequent definitive trial.

### **3. General Study Design**

A feasibility trial of a pragmatic, parallel group patient randomised superiority trial comparing Let's Talk plus treatment as usual (TAU) or TAU alone.

### **4. Interventions to be evaluated**

Let's Talk plus treatment as usual: Let's Talk is an adaptation of the HOP program. HOP comprises of a workbook and manual and is delivered in a group format by one or more facilitators trained in the manual and at least one facilitator that has lived with experience of a mental health problem<sup>3-5</sup>. Let's Talk has been adapted to ensure localisation to the UK context and delivery in a one-to-one setting by a peer support worker with up to 10 weeks of the programme.

Treatment as usual: this includes early intervention in psychosis and secondary care adult mental health services.

### **5. Randomisation, Allocation and Blinding**

All participants who agree to enter the study will be logged with the central trial office and given a unique Study Number. Randomisation will utilise the existing proven remote automated computer randomisation application in the central trial office in the Centre for Healthcare Randomised Trials (CHaRT, a fully registered UK CRN clinical trials unit) in the Health Services Research Unit (HSRU), University of Aberdeen.

Randomisation will be computer-allocated using randomised-permuted blocks of random size. The unit of randomisation will be the participant and on a 1:1 ratio stratified by centre and delivery mode (in person or remote). No blinding of the treatment allocation will be done.

## **6. Outcome Measures**

### **6.1. Feasibility outcomes**

As it is a feasibility study, a single primary outcome is not meaningful. The key outcomes are (these will be tabulated and not analysed):

1. Referral rates;
2. Recruitment;
3. Attendance at the Let's Talk sessions (number of sessions);
4. Fidelity to the Let's Talk strategies and peer principles Follow-up/questionnaire; response rates.

### **6.2. Outcome measures**

Outcomes measures will be collected to determine their suitability for use in a definitive trial and identify a suitable primary outcome for a definitive trial, rather than to draw conclusions about efficacy of treatments. In addition to demographics, we will collect the following outcomes:

1. The Semi-structured Interview Measure for Stigma in Psychosis (SIMS)<sup>6</sup>;
2. Disclosure Stress Scale (DDS)<sup>5</sup>;
3. Stigma Stress Scale<sup>7</sup>;
4. The Process of Recovery Questionnaire (QPR)<sup>8</sup>;
5. The Calgary Depression Rating Scale for Schizophrenia (CDS)<sup>9</sup>;
6. Social Interaction Anxiety Scale (SIAS)<sup>10</sup>;
7. Manchester Short Assessment of Quality of Life Scale (MANSA)<sup>11</sup>;
8. Rogers Empowerment Scale (RES)<sup>12</sup>;
9. Economic patient questionnaire<sup>13</sup>;
10. EuroQol Group's 5-dimension health status questionnaire 5 level (EQ5D-5L)<sup>14</sup>.

### 6.3. Mediators

We will collect data on the below potential mediators of change to determine feasibility of collecting these measures in a definitive trial to answer important hypotheses about mediators:

1. Internalised Shame Scale (ISS)<sup>15</sup>;
2. Self-Esteem Rating Scale (SERS)<sup>16</sup>.

## 7. Timing of Outcome Measurements

Outcome Measure	Baseline	End of treatment (2.5 months <sup>1</sup> )	6 months <sup>1</sup>
SIMS	✓	✓	✓
DDS	✓	✓	✓
Stigma Stress Scale	✓	✓	✓
QPR	✓	✓	✓
CDS	✓	✓	✓
SIAS	✓	✓	✓
MANSA	✓	✓	✓
RES	✓	✓	✓
Economic patient questionnaire	✓	✓	✓
EQ5D-5L	✓	✓	✓
ISS	✓	✓	✓
SERS	✓	✓	✓

<sup>1</sup> post-randomisation

## 8. Progression criteria

The progression criteria to a definitive trial are:

1. Recruitment rate within ≥80% (green); 79-60% (amber); <60% (red) of planned target.
2. Retention of participants within the study with ≥ 80% (green); 79-60% (amber); <60% (red) of data for the Semi-structured Interview Measure of Stigma (SIMS<sup>6</sup>)

or Stigma Stress Scale<sup>7</sup>, which are the proposed primary outcomes for a definitive trial.

3.  $\geq 80\%$  (green); 79-60% (amber);  $<60\%$  (red) of those allocated to Let's Talk receiving at least two sessions.

## 9. Adverse Events

A serious adverse event (SAE) is:

- All death;
- Suicide attempts;
- Serious violent incidents;
- Any other life-threatening incident;
- Admissions to a psychiatric hospital;
- Formal complaints about the study.

Please see the Study Protocol for more details on AEs. The number SAEs and the proportion of participants with an event will be presented. These will be tabulated and not analysed and will be summarised by Intention-to-Treat (ITT) and as treated.

## 10. Sample Size and Power Calculation

Outcome data on 60 participants is needed to estimate the standard deviation (SD) required for a sample size calculation for a definitive trial. We have used the advice from Whitehead et al<sup>17</sup> to plan ahead for a trial with 90% power and potential small-to-moderate effect size (standardised effect size ranging from 0.2 to 0.4). To allow 20% attrition, we will recruit 75 participants. A pilot study of this size will allow to test procedures and gather information on other trial design and process elements that are listed in the objectives section.

## 11. Statistical Methods

### 11.1. General Methods

All the main analyses will be based on the ITT principle. Final analysis will take place after full recruitment and follow-up. The results of the trial will be presented following the Consolidated Standards of Reporting Trials (CONSORT) 2010

Statement: extension to randomised pilot and feasibility trials<sup>18</sup>. As this is a feasibility trial, the main focus will be to summarise baseline and follow-up data using the appropriate descriptive statistics and graphical summaries. However, we will also look at treatment effects which will be presented with 95% confidence intervals (CIs). There will be no adjustment to secondary outcomes for multiple testing. All eligible participants will be included in the analysis and who provided consent. Any post-randomisation exclusions will be removed and reported as such and agreed with the PMG. Model assumptions will be checked and dealt with appropriately. See Appendix (section 16) for how patient reported outcome measures (PROMS) are derived along with Stata code for the analysis of the outcomes.

### **11.2. Interim Analysis**

There are no planned interim analyses for efficacy or futility but an independent Data Monitoring Committee (DMC) will monitor trial progress and specifically any safety issues.

### **11.3. Feasibility Outcomes**

Descriptive statistics will be used to summarise the key indicators of the success of the trial (see section 6.1 for details if these indicators).

### **11.4. Outcome measures**

To inform a definitive trial analysis, the proposed outcomes (see section 6.2, apart from economic patient questionnaire) will be analysed using repeated-measures mixed-effects regression model correcting for baseline score and time as a categorical fixed effect and centre, mode of delivery, and participant as a random effect. The repeated measures will be assessed at 2.5 and 6 months post-randomisation with treatment effects estimates from a time-by-treatment interactions at each time point. Data missing at baseline will be reported as such. For the analysis, missing baseline data will be imputed using the centre-specific mean of that variable. Economic data collected by the economic patient questionnaire will be summarised using appropriate descriptive statistics.

## 11.5. Mediators

The mediators, defined in section 6.3 will be summarised using appropriate descriptive statistics. Mediation analysis aims to decompose a total effect (ITT effect) into an indirect effect, which measures how much of the effect acts through an intermediate variable, and a residual direct effect which measures how much of the effect does not act through the mediator. However, formal analysis will be considered.

## 11.6. Missing Data

## 11.7. Missing Outcome Data

As this is a feasibility study there will be no formal analysis to account for missing data.

## 11.8. Statistical software

All analysis will be carried out in Stata<sup>19</sup> (or the current version available).

## 12. COVID-19

The effect of COVID-19 defined as 11<sup>th</sup> March 2020<sup>20</sup> or after will be explored. In the first instance, periods before, during and after COVID-19 will be summarised using appropriate descriptive statistics and graphical summaries. If need be, formal analysis will be carried out to explore the effect of COVID-19.

## 13. Dummy Tables

**Table 13.1 Feasibility outcomes**

	Let's Talk + TAU N=	TAU N=	Total N=
Referral rates – n (%)	NA	NA	
Recruitment – n (%)	NA	NA	
Attendance at the Let's Talk sessions (number of sessions) <sup>1</sup> – n (%)		NA	
≥ 80%			
60 -79%			
<60%			
Fidelity to the Let's Talk manual and principles of peer support and the most used Let's Talk strategies – n (%)		NA	
Fidelity to peer principles			

Most used strategies (all sessions and by session)	
Fidelity to the Let's Talk strategies – n (%)	NA
Fidelity to peer principles	
Most used strategies (all sessions and by session)	
Follow-up/questionnaire response rates <sup>2</sup> – n (%)	
SIMS Total	
Stigma stress	

<sup>1</sup>of those receiving at least two sessions. This will also be summarised by delivery mode. <sup>2</sup> 2.5 months is the primary end point but 6 months will also be reported.

**Table 13.2 Recruitment by centre**

Centre	Let's Talk + TAU N=	TAU N=
Greater Manchester Mental health NHS foundation trust		
North East London NHS Foundation Trust		

Values are numbers (percent).

**Table 13.3 Baseline characteristics**

	Let's Talk + TAU N=	TAU N=
Age – mean (SD); n		
Gender – n (%)		
Female		
Male		
Nonbinary		
Prefer not to say		
Transgender male		
Transgender Female		
Other		
Highest level of education – n (%)		
Primary		
Secondary		
Further		
Higher		
Employment status – n (%)		
Full-time		
Part-time		
Voluntary		
College student		
University student		
Carer		

---

Unemployed  
Marital status – n (%)  
Single  
Married  
Divorced  
Separated  
Windowed  
Cohabiting  
Civil partnership[  
Living arrangements – n (%)  
Parents  
Partner  
Alone  
Friends  
Carer  
Other  
Ethnicity – n (%)  
White  
Mixed/ Multiple ethnic groups  
Asian/ Asian British  
Black/ African/ Caribbean/ Black British  
Chinese  
Arab  
Other  
Religion/belief – n (%)  
Atheism  
Buddhism  
Christianity  
Islam  
Jainism  
Sikhism  
Judaism  
Hinduism  
Other  
Disclosure stress scale – mean (SD); n  
The process of recovery questionnaire – mean (SD); n  
The Calgary depression scale – mean (SD); n  
Manchester Short Assessment – mean (SD); n  
EQ-5D-5L – mean (SD); n  
Social Interaction Anxiety Scale – mean (SD);  
Rogers Empowerment Scale – mean (SD); n  
The Semi-structured Interview Measure for Stigma in  
Psychosis – mean (SD); n  
Stigma Stress Scale – mean (SD); n  
Self esteem rating scale – mean (SD); n  
Internalised Shame Scale – mean (SD); n

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SD standard deviation



**Table 13.4 Outcome measures**

	Let's Talk + TAU N=	TAU N=	MD	95% CI	p- value
Disclosure distress scale – mean (SD); n					
Baseline					
2.5 months					
6 months					
The process of recovery questionnaire – mean (SD); n					
Baseline					
2.5 months					
6 months					
The Calgary depression scale – mean (SD); n					
Baseline					
2.5 months					
6 months					
Manchester Short Assessment – mean (SD); n					
Baseline					
2.5 months					
6 months					
EQ-5D-5L – mean (SD); n					
Baseline					
2.5 months					
6 months					
Social Interaction Anxiety Scale – mean (SD);					
Baseline					
2.5 months					
6 months					
Rogers Empowerment Scale – mean (SD); n					
Baseline					
2.5 months					
6 months					
The Semi-structured Interview Measure for Stigma in Psychosis – mean (SD); n					
Baseline					
2.5 months					
6 months					
Stigma Stress Scale – mean (SD); n					
Baseline					
2.5 months					
6 months					

SD standard deviation; MD mean difference; CI confidence interval

**Table 13.5 Mediators**

	Let's Talk + TAU N=	TAU N=
Self esteem rating scale – mean (SD); n		
Internalised Shame Scale – mean (SD); n		
Baseline		
2.5 months		
6 months		

SD standard deviation

**Table 13.6 Serious adverse events**

	Let's Talk + TAU N=	TAU N=
Number of serious adverse events – n (%)		
Number of participants with a serious adverse event - n		
Details - n		
Death		
Suicide attempts		
Serious violent incidents		
Any other life-threatening incident		
Admissions to a psychiatric hospital		
Formal complaints about the study		

**Table 13.7 Economics – 2.5 and 6 months**

	Let's Talk + TAU N=	TAU N=
Planned hospital overnight stays		
Yes		
No		
Don't know		
Department stayed in		
Etc.		
Attended hospital outpatient appointments for less than 4 hours		
Yes		
No		
Don't know		
Department or specialty		
Etc.		
Attended hospital outpatient appointments for more than 4 hours (but not overnight)		
Yes		
No		
Don't know		
Department or specialty		

---

Etc.  
Attended Accident and Emergency  
Yes  
No  
Don't know  
Attended any primary and community based health services  
GP (at surgery/practice)  
Yes  
No  
Don't know  
GP at home  
Yes  
No  
Don't know  
Practice nurse (at surgery)  
Yes  
No  
Don't know  
Practice nurse at home  
Yes  
No  
Don't know  
Other physical care services  
Yes  
No  
Don't know  
Walk-in-centre  
Yes  
No  
Don't know  
Other  
Yes  
No  
Don't know  
Mental health services  
Yes  
No  
Don't know  
Counsellor or mental health worker  
Yes  
No  
Don't know  
Other social support services  
Yes  
No  
Don't know  
Other health or social care or support services  
Yes

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No  
Don't know

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Values are numbers (percent)

## 14. Dummy Figures

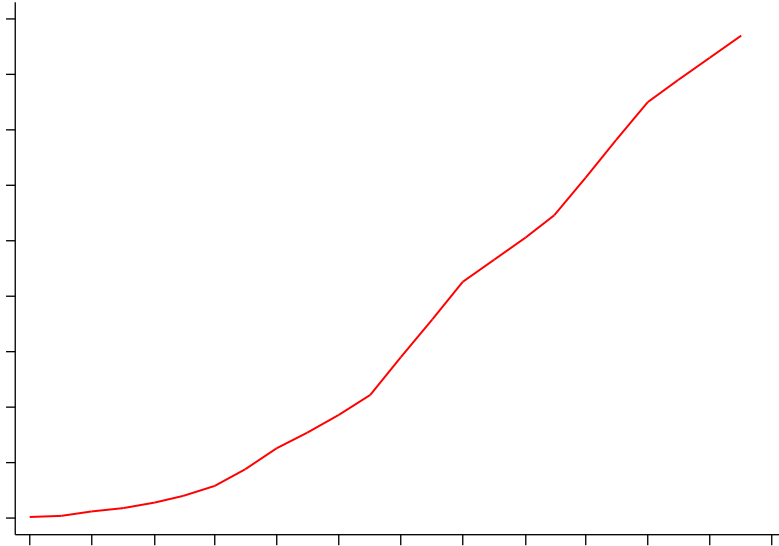
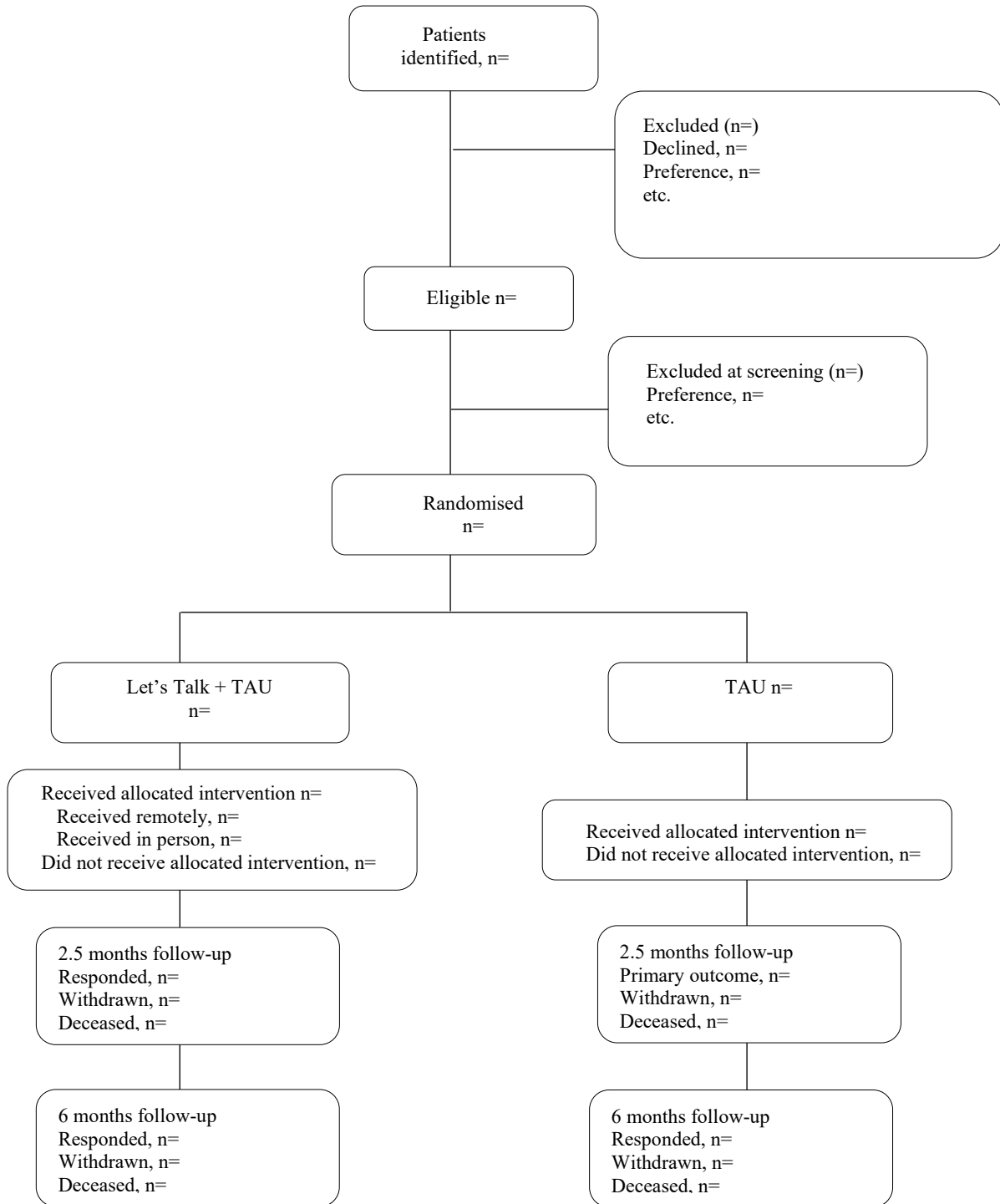


Figure 1 Recruitment graph



**Figure 2 Participant flow**

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## 16. Appendices

### 16.1. Derived Patient reported Outcome Measures (PROMs)

The PROMs are listed in section 6.2 and section 6.3. Codes developed in-house will be checked and validated by an independent statistician using dummy data. Table 16.1 describes how each score will be calculated.

**Table 16.1 Calculation of PROMs score**

PROMs	Calculation
The Semi-structured Interview Measure for Stigma in Psychosis	SIMS comprises of 11 items but only ten are included in the total score (understanding stigma is not included). Each item is scored between 0 (no impact/experience of stigma) to 4, (severe impact/experience of sigma). A total score is calculated by adding up all 10 items and ranges from 0 to 40. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant. Positive impacts are reverse scored.
Disclosure Stress Scale	1 item question, ranging from 1 to 7. <sup>5</sup>
Stigma Stress Scale	An eight-item measure that assesses Cognitive appraisal of stigma as a stressor. Items are rating on a 1-7 point Likert Scale with 1= strongly disagree and 7 = strongly agree. Four items assessed the primary appraisal of stigma as harmful (items 1-4) and four items the secondary appraisal of perceived resources to cope with stigma (items 5-8). A single stress appraisal score is computed by subtracting perceived resources to cope from perceived harmfulness. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
The Process of Recovery Questionnaire	15 item questionnaire. Scoring is from 1 to 5 with 1 = Disagree strongly and 5 = Agree Strongly. a total score is created by adding up all 15 items. <sup>8</sup> Currently

	there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
The Calgary Depression Rating Scale for Schizophrenia	9 item questionnaire, score 0 for absent up to 3 for severe. A total score is calculated but adding up all items and ranges from 0 to 27. <sup>21,22</sup> Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
Social Interaction Anxiety Scale	Scoring is from 0 to 4 with 0 = not at all characteristic or true of me and 4 = extremely characteristic or true of me. A total score is created from the 20 questions with question 5, 9 and 11 reversed. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
Manchester Short Assessment of Quality of Life Scale	Satisfaction scoring across life domains is on a 1-7 Likert Scale with 1 = terrible and 7 = delighted  $\text{MANSA Total Satisfaction} = Q1 + Q2 + Q10a \text{ or } Q10b^* + Q14 + Q18 + Q23 + Q24 + Q28 + Q32 + Q36a \text{ or } Q36b + Q40 + Q43$ * item 10 assess satisfaction with working arrangements. Item 10a to be completed if working and item 10b to be completed if the person is not working. ** item 36 assesses satisfaction with living arrangements item 36a to be completed if the person lives with someone and item 36b to be completed if living alone. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.

Rogers Empowerment Scale	28 item questionnaire, scored between 1 (strongly agree) to 4 strongly disagree. A total score is the sum of all items. <sup>12</sup> Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
EQ-5D-5L	EQ-5D-5L is calculated using value sets available at <a href="http://euroqol.org">Cross-walk – EQ-5D (euroqol.org)</a>
Internalised Shame Scale	Scoring is from 1 to 5 with 1 = never and 5 = almost always. Questions 4, 9, 14, 18, 21 and 28 are reverse scored. Total score is 30 questions added together. Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.
Self-Esteem Rating Scale	Scoring is from 1 to 7 with 1 = never and 7 = always. There are 10 positive and 10 negative items with 10 being scored positively and the other 10 are reversed scored (ones marked with an asterisk). Currently there is no recommendations on when at least one item is missing for a participant. Therefore, if this occurs a total score will not be calculated for this participant.

## 16.2. Stata code

Table 16.2 provides sample Stata code for the analysis, each outcome (see section 6.2) will be analysed the same therefore the code below will be used for all outcomes.

**Table 16.2 Stata code**

Outcome	Stata code
<b>SIMS</b>	<pre> mixed sims sims_b i.letstalk##i.TimePoint    CentreNo:    delevarymode:    StudyNo: </pre> <ul style="list-style-type: none"> <li>• <code>c sims sq</code> is continuous</li> <li>• <code>sims_b</code> is continuous baseline score</li> <li>• <code>letstalk</code> binary (coded 0 for TAU and 1 Let's Talk plus TAU)</li> <li>• <code>TimePoint</code> is a categorical variable corresponds to the follow-up time points (coded 2 = 2.5 months, 6 = 6 months)</li> <li>• <code>CentreNo</code> categorical (corresponds to each recruiting centre)</li> <li>• <code>delevarymode</code> 0 = in person; 1 = remote</li> <li>• <code>StudyNo</code> is a unique participant identifier</li> </ul> <p>Treatment effect for 2.5 months  <code>lincomest _b[1. letstalk]</code></p> <p>Treatment effect for 6 months  <code>lincomest _b[1. letstalk] + _b[1. letstalk #6.TimePoint]</code></p>