Statistical Analysis Plan

Online Hearing Voices Peer Support Groups: A Feasibility and Acceptability Study
Version 1.0

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1. AMENDMENT HISTORY

SAP Version	Protocol Version	Section number changed	Description	Date changed
V1	V1	Initial release	Initial release	29/03/2023

2. INTRODUCTION

2.1 Aim

The primary study objectives are to determine: 1) whether it is feasible to deliver a peer-run hearing voices support group online (HVG) for people who hear voices; and 2) whether the online hearing voices group is acceptable to voice hearers.

The secondary study objectives are: 1) to determine whether it is feasible to conduct a detailed investigation into the possible mechanism of efficacy of online hearing voices group; and 2) being to explore those possible mechanisms of efficacy through qualitative investigations with study participants.

2.2 Study Design

The study is a longitudinal, repeated-measured mixed-methods study comprising two components: 1) a non-randomised feasibility study of an online HVG with a target recruitment sample of 6-10 participants; and 2) a nested qualitative study on the acceptability and potential mechanisms of efficacy of the online HVG.

3. ANALYSIS OBJECTIVES

The objectives are to assess, under non-randomised conditions:

- The number and proportion of eligible participants consenting to take part
- The total number of participants recruited
- The completeness of outcome measures
- Group attendance rates
- Study drop-out rates
- Reason for study withdrawal

4. OUTCOMES

4.1 Primary Feasibility Outcomes

The key outcomes to inform a future trial are referral rates, recruitment, attendance and peer support group meetings, questionnaire completion rates, and follow-up rates. Acceptability of the intervention will be measured using rates of drop-out and participant feedback during qualitative interviews. A specified red/amber/greed progression criteria will be reviewed at the end of the trial to inform recommendations for a definitive trial. The progression criteria are:

- Recruitment ≥ 80% of planned (green), recruitment within 79-60% of planned (amber), recruitment < 60% of planned (red)

- Retention of participants within the study with baseline and outcome assessments and interviews at end-of-study (6 months, end of intervention) ≥ 80% of outcome assessments/interviews completed (green), 79-60% of outcome assessments/interviews completed (amber), < 60% outcome assessments/interviews completed (red)
- Group attendance at each individual group meeting ≥ 80% of total participants (green), group attendance 79-60% of total participants (amber), group attendance < 60% of total participants (red)
- Satisfactory delivery of the online hearing voices group

4.2 Secondary Clinical Outcomes

All secondary outcomes are being collected to determine their suitability for use in a definitive trial, rather than to draw conclusions about clinical efficacy. These include:

- Social Comparison Scale (Allan & Gilbert, 1995)
- Social Connectedness Scale – Revised (SCS-R; Lee, Draper & Lee, 2001)
- UCLA Loneliness Scale Version 3 (Russell, 1996)
- Personal Beliefs about Experiences Questionnaire (PBEQ; Pyle et al., 2016)
- Approve Questionnaires (Hayward et al., 2020)
- Voices Impact Scale (VIS; Strauss, n.d.)
- Voice Acceptance and Action Scale – 12 (VAAS-12; Shawyer et al., 2007)
- Questionnaire about the Process of Recovery – 15 (QPR-15; Neil et al., 2009)
- Group Cohesiveness Scale (GCS; Wongpakaran et al., 2013)
- Therapeutic Factors Inventory – Short Form (TFI-S; MacNair-Semands et al., 2010)

4.3 Endpoints and Covariates (Frequency of Measurements)

	Baseline	4 Weeks	12 Weeks	End-of-Study
Measures of Social Connectedness				
Social Comparison Scale	X			X
SCS-R	X			X
UCLA Loneliness Scale	X			X
Approve – Social	X			X
Measure of voice hearing				
Approve – Voices	X			X
VIS	X			X
VAAS-12	X			X
General clinical presentation				
PBEQ	X			X
QPR-15	X			X
Qualitative interviews	X			X
Group cohesion				
GCS		X	X	X
TFI-S		X	X	X

4.4 Adverse Events

A serious adverse event (SAE) is defined by the Health Research Authority (HRA) as any untoward event that:

- Results in death
- Is life threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Is otherwise considered medically significant by the investigator

An SAE occurring during the course of research will be reported to the Research Ethics Committee (REC) where in the opinion of the PhD student and supervisory team, the event was:

- Related, that is, it resulted from administration of any study procedures, and
- Unexpected, that is, the type of event is not listed in the protocol and adverse events SOP as an expected occurrence.

Adverse events (i.e., self-harm) will also be reported.

5. STATISTICAL METHODS

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.

5.1 Primary Feasibility Outcomes

Descriptive statistics will be used to summarise the key indicators of the success of the trial, including participant recruitment, group attendance, and completion of outcome measures. Appropriate summary statistics will the number of participants referred through mental health staff, the number of participants self-referred, number of referrals found to be eligible, number of consented individuals, number of drop-outs, withdrawals of consent and failure to provide follow-up outcome data.

5.2 Secondary Clinical Outcomes

Summary statistics of the secondary clinical outcomes (Social Comparison Scale, SCS-R, UCLA Loneliness Scale, Approve Scales, VIS, VAAS-12, QPR-15) will be presented. Given the small sample size, the Reliable Change Index (RCI) (Jacobson & Truax, 1991) will be used to detect clinically and statistically significant changes pre- and post-intervention on an individual level. The RCI indicates how much and in what direction an individual has changed, as well as if that change is reliable and clinically significant. RCI for each outcome measure will be calculated using the following equation outlined by Zahra & Hedge (2010) where x_1 and x_2 are the pre- and post-test scores of the participant for whom the RCI is being calculated, s_1 is the standard deviation for the pre-test group and r_{xx} is the test-retest reliability of the measure:

$$RCI = \frac{x_2 - x_1}{\sqrt{2\left(s_1\sqrt{1 - r_{xx}}\right)^2}}$$

RCI with a magnitude of 1.96 in either direction are considered statistically reliable at the $p < .05$ level (Jacobson & Truax, 1991).

While the study is not powered to detect clinical change, in order to understand potential group changes in addition to individual change, a linear mixed-effects regression model will be fit for each outcome with baseline values as fixed effects and the participant as random effects. This model will be based on the intention to treat (ITT) principle. The presentation of the ITT analysis will focus on point estimates and associated 95% confidence intervals rather than statistical significance (p-values), although it is likely we will include p-values in any journal publications. The sensitivities of all treatment effect estimates to missing outcome data arising from drop-out will also be examined.

5.3 Missing Data

As this is a feasibility study, there will be no formal analysis to account for missing data. Data missing at baseline will be reported as such. RCI analysis will not be possible with missing baseline or end-of-study data and will be reported as such. If required for models, continuous data will be imputed with the mean of the missing variable. Binary/categorical data will include a missing indicator.

6. DUMMY TABLES

Table 1. Baseline characteristics

	Total Sample (N =)
Age – mean (SD)	
Gender – n (%)	
Female	
Male	
Non-binary	
Other	
Ethnicity – n (%)	
White Caucasian	
Asian	
Black	
Middle-Eastern	
Mixed-Race	
Other	
Unsure/unspecified	
Marital status – n (%)	
Single	
Married/living with partner	
In a relationship but not living together	
Separated	

- Divorced
- Widow/widower
- Other
- Unsure/unspecified

Employment status – n (%)
- Paid or self-employed
- Voluntary work
- Sheltered employment
- Supported employment (TEP, vocational rehabilitation)
- Unemployed
- Student
- Housewife/husband
- Retired
- Exempt through disability
- Other
- Unsure/unspecified

Highest educational level – n (%)
- Primary education or less
- Secondary education
- Tertiary/further education
- Other general education
- Other
- Unsure/unspecified

Voice hearing duration (years) – mean (SD)

Heard voices continuously since onset – n (%)
- Yes
- No

Diagnosis – n (%)
- Schizophrenia
- Schizoaffective
- Psychosis
- Bipolar
- Depression
- Anxiety
- Post-traumatic stress disorder
- None

Current/past contact with NHS mental health service – n (%)
- Yes
- No

Type of NHS mental health service
- Early intervention in psychosis
- Community mental health team
- IAPT
- Other

Past psychiatric hospitalisation – n (%)
- Yes, multiple times
- Yes, one time
- No

Current psychiatric medication use – n (%)	
Yes	
No	
Past therapy for mental health – n (%)	
Yes	
No	
Past peer support for mental health – n (%)	
Yes	
No	

Table 2. Referral and recruitment of participants by service types

	Referred (N=)	Eligible (N=)	Consented (N=)
Early Intervention for Psychosis			
Community Mental Health Team			
Third-Party/Voluntary Organisation			
Community			

Table 3. RCI analysis for all secondary outcome measures

	Pre-Test	Post-Test	Change	RCI
Social Comparison Scale				
Participant 1				
Participant 2				
Participant 3				
Participant 4				
Participant 5				
Participant 6				
Mean				
SD				
SCS-R				
Participant 1				
Participant 2				
Participant 3				
Participant 4				
Participant 5				
Participant 6				
Mean				
SD				
UCLA Loneliness Scale				
Participant 1				
Participant 2				
Participant 3				
Participant 4				
Participant 5				
Participant 6				
Mean				

- SD
- Approve – Social
  - Participant 1
  - Participant 2
  - Participant 3
  - Participant 4
  - Participant 5
  - Participant 6
  - Mean
  - SD
- Approve – Voices
  - Participant 1
  - Participant 2
  - Participant 3
  - Participant 4
  - Participant 5
  - Participant 6
  - Mean
- VIS
  - Participant 1
  - Participant 2
  - Participant 3
  - Participant 4
  - Participant 5
  - Participant 6
  - Mean
  - SD
- VAAS-12
  - Participant 1
  - Participant 2
  - Participant 3
  - Participant 4
  - Participant 5
  - Participant 6
  - Mean
  - SD
- PBEQ
  - Participant 1
  - Participant 2
  - Participant 3
  - Participant 4
  - Participant 5
  - Participant 6
  - Mean
  - SD
- QPR-15
  - Participant 1
  - Participant 2

Participant 3
Participant 4
Participant 5
Participant 6
Mean
SD

Table 4. Baseline and end-of-study scores for all secondary outcome measures

	All participants (N=) mean (SD)	Adjusted mean difference (SE)	95% CI
Social Comparison Scale			
Baseline			
End-of-Study			
SCS-R			
Baseline			
End-of-Study			
UCLA Loneliness Scale			
Baseline			
End-of-Study			
Approve – Social			
Baseline			
End-of-Study			
Approve – Voices			
Baseline			
End-of-Study			
VIS			
Baseline			
End-of-Study			
VAAS-12			
Baseline			
End-of-Study			
PBEQ			
Baseline			
End-of-Study			
QPR-15			
Baseline			
End-of-Study			

Table 5. Incidence of adverse events

	All participants (N=)
Serious Adverse Events	
Participants with an SAE	
Number of SAEs	
Types of SAE	
Death	

Life threatening (suicide attempt)
Life threatening (other)
Voluntary psychiatric admission
Involuntary psychiatric admission
Adverse Events
Participants with an AE
Number of AEs
Types of AE
Self-harm

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