RESEARCH PROTOCOL

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

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1) RESEARCH TEAM & KEY CONTACTS

Chief Investigator:	***Co-investigator(s):***
Name: Dr Filippo Varese (Academic Supervisor) Address: Faculty of Biology, Medicine and Health 2.40 Zochonis Building University of Manchester Oxford Road, Manchester M13 9PL Email: Filippo.varese@manchester.ac.uk Telephone: 0161 306 0434	Name: Ms Alison Branitsky (PhD Student) Address: Faculty of Biology, Medicine and Health 2.43 Zochonis Building University of Manchester Oxford Road, Manchester M13 9PL Email: alison.branitsky@postgrad.manchester.ac.uk Telephone: 07936 813441
Sponsor(s):	***Lead R&D Trust contact(s):***
Name: The University of Manchester Sponsor contact: Ms Lynne Macrae, Faculty Research Practice Governance Coordinator Address: Faculty of Biology, Medicine and Health 5.012 Carys Bannister Building University of Manchester M13 9PL Email: FBMHethics@manchester.ac.uk Telephone: 0161 275 5436	Name: Sarah Leo Address: Greater Manchester Mental Health NHS Foundation Trust R&I Office, Harrop House Bury New Road Prestwich, M25 3B Email: researchoffice@gmmh.nhs.uk Telephone: 0161 271 0084

Co-investigator: Name: Prof Sandra Bucci (Academic Supervisor) Address: Faculty of Biology, Medicine and Health 2.15 Zochonis Building University of Manchester Oxford Road, Manchester M13 9PL Email: Sandra.bucci@manchester.ac.uk Telephone:	***Co-investigator:*** Name: Prof Tony Morrison (Academic Supervisor) Address: Faculty of Biology, Medicine and Health 2.30 Zochonis Building University of Manchester Oxford Road, Manchester M13 9PL Email: tony.morrison@gmmh.nhs.uk Telephone: 0161 358 1395
Co-investigator: Name: Dr Eleanor Longden (Academic Supervisor) Address: Faculty of Biology, Medicine and Health Psychosis Research Unit Harrop House Bury New Road, Prestwich M25 3BL Email: Eleanor.longden@gmmh.nhs.uk Telephone: 0161 358 1395	

2) INTRODUCTION

Hearing voices that nobody else can hear (auditory hallucinations) can be a distressing and isolating experience. Previous research has shown that meeting others with similar experiences can help people feel less isolated, cope better with their voice hearing experiences, and experience more hope for the future. While there are many peer support groups for voice hearers that meet face-to-face, many people cannot access these groups. The purpose of this project is therefore to see if it is possible to deliver a peer support group for voice hearers online.

Six to ten adults who live in the UK and currently hear voices will be recruited to take part in the online hearing voices group. Participants will be recruited from secondary NHS mental health services, third-party mental health organisations, and the wider community. Participants will take part in a 1-to-1 interview and complete questionnaires about their voice hearing experiences before the peer support group starts. The group will then meet once a week for 90 minutes for 6 months. In the group, participants can talk about their voices, explore how their voices make them feel, what their voices may be connected to, and learn new ways of understanding and coping with voices. At the end of the 6 months, participants will complete another interview, asking about their experiences within the group, and complete the same questionnaires.

The purpose of this study is to see if it is possible to run a peer support group for voice hearers online and if so, to start to explore how and why these groups may be beneficial. It is the hope that if these groups prove to be effective, they can be rolled out on a more wide-spread basis within the NHS.

3) BACKGROUND

Hearing voices peer support groups (HVGs) are an integral part of the Hearing Voices Movement (HVM), an international, survivor-led initiative of voice hearers and their allies that promotes a non-biological, person-centred, recovery-oriented approach to voice hearing. HVM rejects the traditional psychiatric assumption that voice hearing is a biogenetic pathology and instead locates voice hearing as a complex psychological experience imbued with personal, relational, and cultural meaning. As such, the HVM promotes the idea that voice hearing experiences should be explored within the context of

one's life. The role of HVGs is precisely to enable such a practice. HVGs were first established in 1988 and have since proliferated across the world, with groups now based in over 30-countries (Corstens et al., 2014).

Despite their widespread, only a few studies have looked at the effectiveness and potential mechanisms of action of HVGs in the community. Several small-scale qualitative and quantitative studies suggest that HVGs may be effective at increasing social connectedness, improving self-esteem, facilitating the acceptance of oneself as a voice hearer and imparting new ways of understanding and coping with voices (Beavan et al., 2017; Longden et al., 2018). It is difficult however, to draw conclusions about group effectiveness as these studies were uncontrolled and had no comparator group. Several more studies have looked at key features of HVGs which may serve as potential mechanisms of action. In particular, the acceptance of all interpretive frameworks for voice hearing, democratic group structure and explicit focus on building genuine, mutual relationships are identified as features that may facilitate change (Beavan et al., 2017; dos Santos & Beavan, 2015; Hornstein et al., 2020, 2021; Oakland & Berry, 2015; Payne et al., 2017; Rácz et al., 2017; Schafer et al., 2017).

There are significant methodological challenges in studying HVGs. As the groups propose no intended outcome, traditional pre-post measures on various psychiatric constructs are often inappropriate (Hornstein et al., 2020). Furthermore, group members often have very different reasons for attending the group, which presents difficulty in terms of capturing the most suitable outcomes to measure (Hornstein et al., 2021). Finally, as groups have been developed explicitly to be an alternative to more traditional psychiatric offering for voice hearers, there is danger in research into HVGs co-opting the groups and imposing a too rigid structure to their evaluation (Corstens et al., 2014). As such, Hornstein et al. (2020) propose that even in the absence of robust efficacy/effectiveness literature, it is necessary to focus research into potential mechanisms of action to hone in on precisely *how* groups work, both on the individual and group level. The current study proposes to follow this recommendation by conducting a controlled analysis on HVGs looking at feasibility and acceptability, while simultaneously beginning to look at potential mechanisms of efficacy.

Due to the national lockdowns and social distancing measures resulting from COVID-19 in early 2020, many HVGs were forced to adapt to taking place online. The shift to online HVGs coincided with a global shift toward more widespread digital mental health support. While research into all forms of digital mental health support for voice hearers is still in its early stages, studies by Lecomte et al. (2021) and Wood et al. (2021) indicate that psychotherapy delivered via videoconference is an acceptable form of support for voice hearers. Furthermore, peer support delivered digitally has been demonstrated to be feasible (Fortuna et al., 2020), and can improve feelings of personal recovery (Thomas et al., 2016), especially when the intervention comprised of personal testimony from peers (Williams et al., 2018). Taken together, online HVGs may represent a promising form of support for voice hearers.

This study will be the first longitudinal, mixed-methods study of an online HVG. The HVG will run weekly for 90 minutes for a duration of 6 months. Feasibility and acceptability data will be collected, as well as data on potential mechanisms of efficacy.

4) STUDY OBJECTIVES

4.1 Primary Objectives

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

4.2 Secondary Objectives

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 groups; and 2) begin to explore those possible mechanisms of efficacy through qualitative investigations with study participants.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

6-10 adults who live in the UK and currently hear voices will be recruited for this study.

5.2 Study Setting

This study will take place across Community Mental Health Teams (CMHTs) and Early Intervention in Psychosis Team (EIT) services in Greater Manchester Mental Health NHS Foundation Trust (GMMH). Furthermore, participants from third-sector/voluntary organisations across England will also be recruited.

5.3 Study Design

This is a longitudinal, repeated-measures, 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.

5.3 Study Intervention and Procedures

The first stage of research will be the baseline assessment, consisting of a qualitative research interview and quantitative measures. Interviews will take place via Zoom or MS Teams, per participant preference. Participants will be advised to join the meeting from a quiet, private location. All interviews will be audio-recorded using Zoom or MS Teams' built-in encrypted recording device. Participants will be advised (and detailed on the PIS) that Zoom automatically records both audio and video files and that MS Teams automatically records both audio and video together in one file. In cases where the interview takes place over Zoom, the video file will be deleted immediately after the interview is finished. Where the interview takes place on MS Teams, the video will be retained until after transcription is complete. A topic guide (attached) which was developed in consultation with PPIE representatives will be used during the interviews and it is expected that interviews will last about 1 hour. Following the interview, participants will be asked to complete a series of quantitative measures assessing social connections, voices, and sense of personal recovery. They will be sent an email containing their participant ID and a link to the measures. These measures will be completed online via Qualtrics and are expected to take approximately 30 minutes to complete. The survey will be linked to the participant via participant ID. If participants need assistance completing the measures, they can be completed via videoconference with the researcher. Participants will be

compensated £20 in either cash, bank transfer or shopping/Amazon voucher for completing the baseline assessment.

After all participants have completed the baseline assessment, the online peer support group will commence. The online peer support group will meet for 90 minutes each week for 26 weeks. The group will be facilitated by the researcher, who is a trained hearing voices peer support group facilitator, and a clinically-qualified psychologist from the NHS. This would ensure that a clinically qualified individual would immediately be able to address any safeguarding concerns that may arise. Furthermore, as part of the purpose of this study is to begin to understand how online HVGs could be integrated into the NHS, it would be useful to ascertain how having clinically qualified individuals impacted the group dynamics. The group will take place on Zoom or MS Teams, as these are university-supported videoconferencing platforms and recommended by PPIE representatives. Participants will be provided with the joining details for the HVG ahead of the first group, and those details will remain unchanged for the entire duration of the study.

In line with the ethos of the HVM, groups will remain relatively unstructured but will focus broadly on exploring participants' voice hearing experiences. One of the values of HVGs is to promote dialogue and mutual support and exploration; as such, group members will be encouraged to talk to one another, rather than the facilitator, share stories and strategies for managing their voices, and explore the content and meaning of their voices. Additional emphasis will be placed on exploring the connections between voices and life experiences and exploring ways of improving the relationship between voice-hearers and their voices. Should additional structure be necessary in order to encourage dialogue within the group, resources such as Eleanor Longden's TED Talk, *The Voices in My Head* (Longden, 2013), the short film, *Beyond Possible: How the Hearing Voices Approach Transforms Lives* (Hornstein et al., 2019), and information about voice constructs (Romme & Escher, 2000), compassionate responses to voices (Heriot-Maitland & Longden, 2022) and voice dialogue (Longden et al., 2021) will be shared and discussed.

During the HVG, participants will be advised that they can turn off their camera if they wish. No recordings, either audio or video, will be made of any of the group sessions.

Feasibility data (e.g., retention) will be collected at each group meeting and AB will keep a reflective log of each group meeting.

At weeks 4 and 12, participants will complete quantitative measures of group cohesiveness. This survey will be sent to participants via email and completed on Qualtrics. If participants need assistance completing the measures, they can be completed over videoconference with the researcher.

All participants will then complete an end-of-study assessment, consisting of a qualitative research interview and quantitative measures. Interviews will take place via Zoom or MS Teams, per participant preference. Participants will be advised to join the meeting from a quiet, private location. All interviews will be audio-recorded using Zoom or MS Teams' built-in encrypted recording device. Participants will be advised (and detailed on the PIS) that Zoom automatically records both audio and video files and that MS Teams automatically records both audio and video together in one file. In cases where the interview takes place over Zoom, the video file will be deleted immediately after the interview is finished. Where the interview takes place on MS Teams, the video will be retained until after transcription is complete. A topic guide (attached) which was developed with PPIE representatives will be used during the interviews and it is expected that interviews will last about 1 hour. Following the interview, participants will be asked to complete a series of quantitative measures assessing social connections, voices, and sense of personal recovery. These measures will be completed online via Qualtrics and are expected to take approximately 30 minutes to complete. If participants need assistance completing the measures, they can be completed over videoconference with the researcher. Participants will be compensated £20 in cash, bank transfer or shopping/Amazon voucher for completing the end-of-study assessment.

5.3 End of study

The study will be defined as having ended when all participants have completed the end-of-study assessment.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria

(1) Aged 18 or older
(2) Currently residing in the UK
(3) Heard voices for at least 6 months
(4) Able to provide informed consent
(5) Willingness to engage in group support
(6) Consistent access to the internet and ability to use videoconferencing platforms

6.2 Exclusion Criteria

(1) At immediate risk of harm to self or others
(2) Non-English speaking as assessment measures are only validated in English and in order for group support to function, participants need to be able to communicate with one another

6.3 Recruitment

NHS Trusts

Individuals who currently hear voice and who are receiving mental health services from within GMMH CMHTs or EIT services will be recruited for this study. Potential participants will be initially identified by GMMH staff. Staff will be sent posters and leaflets for both participants and referrers and will be asked to put participant leaflets in public areas such as waiting rooms. Study advertisements will likewise be displayed on GMMH splash screens. AB will attend team meetings to present the study, explain the rationale, methodology, intended outcomes and safeguarding procedures, and answer any questions the staff may have. Potential participants will be identified through current healthcare professionals reviewing their own records and advertising the study using leaflets and posters to potentially eligible participants. The precise procedure for contacting, confirming eligibility and consenting potential participants will follow the policies of the respective clinical team to reduce unnecessary burden on the healthcare professional. Nevertheless, the procedure will generally adhere to the following policy:

1. The healthcare professional will initiate the first contact and explain the study to the individual.

2. If the individual expresses interest in the study, they will verbally consent to the healthcare professional to have their contact details passed on to AB. Employing a verbal consent method has been employed in other feasibility studies undertaken by the supervisory team and reduces the burden on the healthcare professional. In teams where the consent to contact needs to be more formalized, a Consent to Contact form will be completed and send to AB.
3. AB will arrange a call with the referring healthcare professional to obtain the participant's contact information, gain risk information, and complete the Referral to Study form.
4. AB will contact the potential participant to explain the study in more detail, assess eligibility, answer any questions, and see if they are still interested in participation. If the participant is still interested, they will be sent the Participant Information Sheet (PIS) via email (due to the online nature of the group and necessity of technological literacy amongst participants) and be informed that they have a minimum of 24 hours to review the information. They can continue to review the information up until 2 weeks before the start of the group before deciding whether to take part.
5. If a participant is interested in taking part in the study, they will get in touch with AB, who will schedule a call with them to answer any questions, complete the Consent Form (CF), and complete the baseline interview and assessment.
6. AB will inform the participant's care team of their intention to participate in the study.

Third Sector and Voluntary Organisations

Recruitment will also take place through voluntary organisations that support voice hearers (e.g., English Hearing Voices Network, Leeds Survivor Led Crisis Service, Organic Recovery Learning Community). Staff will be sent posters and leaflets for both participants and referrers and will be asked to put participant leaflets and posters in public areas such as waiting rooms. AB will present study information at group meetings attended by staff and open to potential participants. In cases where there is the potential for direct contact with potential study participants, this contact will be mediated by the staff at the respective

organisations. AB will also distribute leaflets and advertising materials to be shared amongst the organisation. The following steps will be followed to identify and contact potentially eligible participants:

1. Participant expresses interest by contacting AB directly via the email or phone number provided on the study advertisement
2. AB will schedule a call with the potential participant to discuss the study, assess eligibility, answer any question, and see if they are still interested in participating. If so, AB will distribute the PIS via email and will inform the participant they have a minimum of 24 hours to review the information and can continue to review it up until 2 weeks before the start of the group before having to make a decision about whether to participate.
3. If a participant is interested in taking part in the study, they will get in touch with AB, who will schedule a call with them to answer any questions, complete the Consent Form (CF), and complete the baseline interview and assessment.

Social Media

Study advertisements will be posted on social media sites including Facebook, Reddit and Twitter using study-specific social media accounts. If a potential participant is interested, the following steps will be followed:

1. Participant expresses interest by contacting AB directly via the email or phone number provided on the study advertisement.
2. AB will schedule a call with the potential participant to discuss the study, assess eligibility, answer any question, and see if they are still interested in participating. If so, AB will distribute the PIS via email and will inform the participant they have a minimum of 24 hours to review the information and can continue to review it up until 2 weeks before the start of the group before having to make a decision about whether to participate.
3. If a participant is interested in taking part in the study, they will get in touch with AB, who will schedule a call with them to answer any questions, complete the Consent Form (CF), and complete the baseline interview and assessment.

6.5 Participants who withdraw consent

Participants will be informed that taking part in the study is voluntary and that consent can be withdrawn at any point without giving a reason and without their care or legal rights being affected. A participant will be withdrawn from the study if they express to AB or to a member of their GMMH care team that they wish to withdraw from the HVG, from the study, or both. If a participant withdraws from the study, a Withdrawal Form will be completed, future data collection will be suspended, and only data collected before the point of withdrawal will be retained. If a participant withdraws from the HVG, but not the study overall, they will still be invited to participate in the end-of-study interview (with the intention of understanding the reason for their withdrawal) and complete the quantitative measures. Participants who withdraw from the study will have the option to remove their data from the study, or have their data retained for analysis. Participants will be advised on the PIS and CF that once the data have been anonymised, it will not be possible to remove their data.

7) OUTCOME MEASURES

The primary objective of this study is to assess the feasibility and acceptability of an online HVG for individuals who hear voices. While additional outcomes will be collected, there will be no formal attempt to establish efficacy of the group.

7.1 Feasibility

In line with the CONSORT (Eldridge et al., 2010) statement for feasibility studies, the following data will be collected: 1) number of eligible participants consenting; 2) total number of participants recruited; 3) completeness of outcome measures; 4) group attendance rate; 5) study drop-out rate; and 6) reason for withdrawal.

7.2 Acceptability

To assess the acceptability of the online HVG, all study participants will complete an end-of-study interview. Topic guides have been developed with PPIE representatives and will cover how well the group met expectations, overall impressions of the group, barriers and facilitators to engagement with the group, and any changes they would make to the group.

7.3 Potential Mechanisms of Efficacy

While the purpose of this study is not to determine efficacy or mechanisms of efficacy for online HVGs, some potential mechanisms will nevertheless be explored to inform a definitive trial in the future. Potential mechanisms of efficacy will be assessed both with validated quantitative measures (outlined below) and with one-to-one interviews. The interview topic guide has been developed alongside PPIE representatives and focuses on experiences within the group, relational dynamics between group members, and impact of group participation.

Quantitative Measures

The *Social Comparison Scale* (Allan & Gilbert, 1995) is an 11-item self-report measure of social comparison and social rank. The scale contains three dimensions: rank (six items: e.g., inferior-superior), attractiveness (two items: e.g., unattractive-more attractive), and similarity to others (three items: e.g., insider-outsider). Items are scored on a 10-point bipolar scale. The scale demonstrated strong internal reliability: $\alpha = 0.91$.

The *Social Connectedness Scale-Revised* (SCS-R; Lee, Draper & Lee, 2001) is a 20-item self-report measure of the extent to which individuals feel connected to others in their social environments. The scale contains items such as: “I am able to relate to my peers,” “I find myself actively involved in people’s lives,” and “I feel distant from people” [reverse scored]. Items are scored on a six-point Likert scale ranging from “strongly disagree” (1) to “strongly agree” (6). The scale demonstrated strong internal reliability: $\alpha = 0.92$.

The *UCLA Loneliness Scale Version 3* (Russell, 1996), is a 20-item self-report measure of loneliness and social isolation. It is a unidimensional measure containing items such as: “How often do you feel that there is no one you can turn to?” and “How often do you feel that no one really knows you well?” Items are scored on a 4-point Likert scale ranging from “never” (1) to “always” (4). The scale demonstrated strong internal reliability: $\alpha = 0.89 – 0.94$.

The *Personal Beliefs about Experiences Questionnaire* (PBEQ; Pyle et al., 2016) is a 13-item self-report measure of negative beliefs in individuals diagnosed with psychotic

disorders. The measure contains three subscales: negative expectations/appraisals (four items: e.g., "I am capable of very little as a result of my experiences"), internal shame/defectiveness (five items: e.g., "there must always have been something wrong with me as a person to have caused these experiences"), and external shame: (four items: e.g., "I am embarrassed to talk about my experiences). Items are scored on a four-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (4). Good internal reliability was reported for the internal shame/defectiveness subscale: $\alpha = 0.70$ and the external shame subscale: $\alpha = 0.81$ (Taylor et al., 2015). Acceptable internal reliability was demonstrated for the negative expectations/appraisals subscale: $\alpha = 0.53$ (Taylor et al., 2015).

The *Approve Questionnaires* (Hayward et al., 2020) are 2 15-item self-report measures of assertive relating to voices (Approve-Voices) and assertive relating to others (Approve-Social). Both scales contain the same questions which contain 3 subscales: assertive relating (five items: e.g., "standing up for myself), aggressive relating (five items: e.g., "shouting and screaming"), and passive relating (five items: e.g., "doing what they want). Items are scored on an 11-point Likert scale ranging from "disagree completely" (0) to "agree completely" (10), with an "N/A" option as well. Good internal reliability was reported for the three subscales of Approve-Voices: assertive relating: $\alpha = 0.85$, aggressive relating: $\alpha = 0.86$, and passive relating: $\alpha = 0.83$ and the three subscales of Approve-Social: assertive relating: $\alpha = 0.79$, aggressive relating: $\alpha = 0.88$, and passive relating: $\alpha = 0.81$.

The *Voices Impact Scale* (VIS; Strauss, n. d.) is a 24-item self-report measure of the emotional impact of voice hearing. Items include: "I have felt anxious because of voices" and "Voices have made my life better." Items are scored on an 11-point Likert scale ranging from "completely disagree" (0) to "completely agree" (10), with an "N/A" option as well. Psychometric properties for this scale have not been reported.

The *Voice Acceptance or Action Scale-12* (VAAS-12; Shawyer et al., 2007) is a 12-item self-report measure of acceptance-based attitudes and actions toward commanding voices. The measure contains two subscales: acceptance (eight items: e.g., "I accept the fact that I hear voices") and action (four items: e.g., "When I disagree with a voice, I simply notice it and move on). Items are scored on a five-point Likert scale ranging from "strongly

disagree" (1) to "strongly agree" (5). The scale demonstrated good internal reliability: α = 0.76.

The *Questionnaire about the Process of Recovery-15* (QPR-15; Neil et al., 2009) is a 15-item self-report measure of recovery from psychosis. The scale was developed in collaboration with service users and focuses on social recovery and general wellbeing, as opposed to symptom cessation. The measure contains two subscales: intrapersonal (11 items: e.g., "I feel that my life has purpose) and interpersonal (four items: e.g., "I am able to develop positive relationships with other people"). Items are scored on a five-point Likert scale ranging from "disagree strongly" (1) to "agree strongly" (5). Good internal reliability was reported for both subscales: intrapersonal: α = 0.94, interpersonal: α = 0.77.

The *Group Cohesiveness Scale* (GCS; Wongpakaran et al., 2013) is a 7-item self-report scale of group cohesiveness developed for group psychotherapy. The scale consists of two subscales: cohesiveness (two items: e.g., "I feel accepted by the group") and engaged (five items: e.g., "The members like and care about each other"). Items are scored on a five-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (5). The scale demonstrated strong internal reliability: α = 0.87.

The *Therapeutic Factors Inventory-Short Form* (TFI-S; MacNair-Semands et al., 2010) is a 23-item self-report measure adapted from the longer Therapeutic Factors Inventory. The TFI-S focuses on four out of 11 of Yalom's therapeutic factors: instillation of hope (six items: e.g., "The group helps me feel positive about my future"), secure emotional expression (seven items: e.g., "I feel a sense of belonging in the group"), awareness of relational impact (six items: e.g., "I pay attention to how others handle difficult situations in my group so I can apply these strategies to my own life"), and social learning (four items: e.g., "Because I've got a lot in common with other group members, I'm starting to think that I may have something in common with people outside the group too"). Items are scored on a seven-point Likert scale ranging from "strongly disagree" (1) to "strongly agree" (7). The subscales demonstrated good internal reliability: instillation of hope: α = 0.91, secure emotional expression: α = 0.86, awareness of relational impact: α = 0.82, and social learning α = 0.71.

8) DATA COLLECTION AND CONFIDENTIALITY

8.1 Data Collection

Data collection will take place in line with the aforementioned procedures. Interview data will be collected via one-to-one interviews at baseline and end-of-study. Quantitative outcomes will be collected via Qualtrics at baseline, 4-weeks, 12-weeks and end-of-study. Feasibility data will be recorded by the researcher during each peer support group.

8.2 Confidentiality

The following steps will be taken to ensure confidentiality during the course of the study:

1) All participants will be assigned a participant number. Questionnaire data will only be linked to a participant via participant number. Participants will be sent an email with their participant ID prior to them completing each questionnaire and they will be asked to input this ID on the questionnaire. Participant names and other identifying information will be removed from all transcripts. A pseudonymisation key will be stored electronically and separately from all research data (the pseudonymisation key will be stored on the P: Drive and all research data will be stored on the Research Data Management System (RDMS)). The pseudonymisation key will be permanently deleted following completion of all study procedures and data analysis, at which point the dataset will be fully anonymised.

2) Interview transcripts will be pseudonymised by removing any information that could identify the participant and replacing it with a generic description (e.g., 'Manchester' would be changed to '[name of city]'). This will be done for all information that could contribute to the identification of the participant or other.

3) Data containing personal information will be stored separately from pseudonymised research data. Personal information will be stored on the University's P: Drive, and all research data will be stored on the RDMB.

4) Interview data will be transferred immediately from the recording device (including Zoom/MS Teams server) to the RDMS. The recording will then be permanently deleted from the recording device.

5) Interviews will be transcribed primarily by the researcher (AB). However, where third parties are required to assist with transcription, they will:

a. Be students from the University of Manchester, meaning data will not have to be moved/shared from the University's secure network.

b. Sign a strict confidentiality agreement (found at Appendix B of University Standard Operating Procedures document titled: taking recording of participants for research projects).

c. Have access to recordings only (not consent forms, demographic information, or questionnaires).

d. Complete transcription on University property or in their private residence using a University laptop connected to the University's secure VPN. As such, the audio recordings and transcripts will not have to be transferred/shared from the University's secure network.

6) Recordings of interviews will be permanently deleted from the University server as soon as possible following transcription.

7) Where participants indicated they would like to receive information about study findings, be invited to take part in member checking, or receive information about future studies, a record will be made and stored separately and securely on the P: Drive, separate from the research data.

7) The limits of confidentiality will be outlined on the PIS. Confidentiality will only be broken if there is a risk of harm to the participant or other. In such an event, the researcher will inform the supervisory team at the earliest opportunity. Where appropriate, the participant will be informed that confidentiality will need to be broken. However, where informing a participant would increase risk or jeopardise a potential safeguarding investigation, they will not be informed.

8) At the beginning of each online peer support group meeting, it will be reiterated that all personal information shared within the group is to be kept confidential.

Participants will be advised that they do not need to share their full name or contact information with other participants, and that they should only share what they are comfortable with within the group.

9) Ineligible participants will have their telephone screening proforma deleted immediately and permanently. These participants will be counted for CONSORT reporting purposes, but no personal data will be retained.

10) Consent forms and participant data will be retained in line with the University of Manchester's Records Retention schedule. Following the minimum retention period of five years, all research data will be permanently deleted from University servers. After a minimum retention period of seven years, all consent forms will be deleted from University servers.

11) Where participants request compensation via shopping voucher, the participant's name and email address will be passed along to the University of Manchester's Finance Department (as outlined in the PIS and CF). This is to enable the Finance Department to send the voucher to the participant electronically. The data will be retained for a minimum period of seven years, in line with the Records Retention Schedule.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

Appropriate descriptive statistics (e.g., mean and standard deviation for continuous data; counts and percentages for categorical data) will be used to summarise: 1) feasibility measures in line with the CONSORT recommendations outlined above; 2) completeness of outcome measures; and 3) reason for withdrawal.

Linear regression models will be fit for each outcome measure with baseline measures of the outcome as fixed effects and the participant and group (in the event of multiple groups) as random effects.

In instances where a participant has completed a questionnaire, but not completed all questions within the questionnaire, the instrument-specific established procedures for

handling partially-missing data will be adhered to. When data are completely missing for a whole questionnaire, this will be noted.

9.2 Qualitative Analysis

Participant interviews will be transcribed verbatim by AB or a member of the research team as soon as possible after the interview. To ensure confidentiality, all personal or identifiable information will be pseudonymised during the transcription process, and each participant will be given a unique pseudonym. Following transcription, audio recordings will be destroyed.

In order to answer questions about acceptability, the interviews will be analysed using Framework analysis, a commonly-used and suitable method of analysis for acceptability studies within applied health and social care research (Spencer et al., 2003). The purpose of Framework analysis is to answer discrete questions about acceptability by generating descriptions and explanatory conclusions clustered around themes. Framework analysis enables both theme-based and case-based analysis through the development of matrix tables that can be read across (cases) or down (themes) (Ward et al., 2013). Framework analysis adopts an ontological realist and an epistemologically flexible approach to research, and should be understood as a method of data analysis, as opposed to a research paradigm (Ritchie et al., 2003). Framework analysis possesses both the methodological rigour and transparency necessary for acceptability studies within health and social care, while maintaining the flexibility that is the hallmark of qualitative research (Swallow et al., 2011).

Data will be analysed using the following method. First, a process of data familiarisation will be undertaken, in which transcripts will be read and any early themes will be noted. This process sensitises the researcher to identify the within- and between-participant differences (Iliffe et al., 2015). Next, a thematic framework will be identified by identifying the key codes that exist within the transcripts (Iliffe et al., 2015). Transcripts will then be indexed by numerically annotating the data to find commonalities and consistencies (Iliffe et al., 2015). Data will then be charted in order to synthesize the codes and develop a final

coding framework (Iliffe et al., 2015). Finally, themes will be mapped graphically on to a matrix and interpreted in light of the research question (Iliffe et al., 2015).

Framework analysis theory emphasizes the researcher's active role in data generation and knowledge production and codes are representations of the researcher's interpretation of patterns of meaning across the dataset (Byrne, 2021). Accordingly, no two researchers would be expected to generate the same codes. As such, in this study, consensus among multiple coders will not be sought. However, in order both to sense-check and explore multiple assumptions and interpretations of the data (Byrne, 2021), codes and subsequent themes will be discussed with the supervisory team and PPIE experts.

9.3 Sample Size

A sample of between 6-10 participants will be both sufficient and manageable given the limited resources of this study. Preliminary evidence arising from qualitative interviews with group facilitators in Study 1 of this PhD, as well as feedback from PPIE experts, indicate that a minimum of 6 participants are needed to ensure sufficient diversity of participant experiences and to enable adequate flow of dialogue within the group. The group will be capped at 10 participants as group facilitators have noted that having groups with more than 12 participants total (including facilitators) becomes unmanageable online and can inhibit the flow of dialogue. 6-10 participants will also enable saturation of qualitative data (see below for an outline of the qualitative analysis). As this is a feasibility study, the study is not powered to detect effects in quantitative measures between baseline and end-of-study.

9.4 Member Checking

To enhance the validity and rigour of the data, the findings will subject to member checking by the study participants. Once the data have been analysed and preliminary themes and sub-themes have been generated, all participants who consented to member checking will be send a copy of the themes to verify that their experience maps onto the themes. Participants will be advised that the themes are meant to broadly capture all the different experiences endorsed, so their personal experiences may not align completely with each theme or sub-theme. Participants will be asked to provide either written or verbal feedback

on the clarity of the themes and accuracy of the interpretation. Specifically, participants will be asked if their experiences are fully captured by the themes and sub-themes, if they themes are sufficiently relevant and necessary to include, and if the interpretations are fair and representative (Creswell, 2005).

9.5 PPIE Consultation

At their core, HVGs are survivor-led initiatives; as such, it is imperative that various stakeholders have input at all stages of study design and delivery. Given the historic tension between the HVM and research bodies, AB has sought informal PPIE input from current members of the English HVN, including HVM leaders/trainers, group facilitators, activists and HVG participants. The consensus has been that given the structure of mental health care in the UK, it would be beneficial to establish a stronger evidence base for HVGs to enable them to be incorporated into NHS settings in the future, thus making them more widely available to voice hearers. These consultants have emphasised the importance fully maintaining HVM values within the constraints of research regulation.

Ongoing input will be sought from the Psychosis Research Unit and Complex Trauma and Resilience Research Unit PPIE advisory groups during the delivery of this study. Specifically, they have advised on the most appropriate inclusion criteria for this study, and provided feedback on the PIS, quantitative measures, and topic guides. Based on their recommendations, the topic guides have been amended to ask about adverse life events. Ongoing input will be sought on the interpretation and dissemination of study result

10) MONITORING AND QUALITY ASSURANCE

This study will be subject to the audit and monitoring regime of the University of Manchester.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

Part of ensuring safety in clinical research is to ensure that serious adverse events (SAEs) are not a direct result of the intervention being tested or any qualitative or quantitative study procedures. As such, adverse events will be monitored, documented and followed up from the time that the participant is enrolled until the end of completion of the study.

Full procedures for monitoring and reporting adverse events can be found in SOP Adverse Events Procedures (attached). In short, an adverse event (AE) is defined as any untoward medical or psychological occurrence that takes place while a participant is enrolled in the study. A serious adverse event (SAE) and serious adverse reactions (SAR) are adverse events that result in death; life-threatening injury; requires hospitalisation or prolongation of existing hospitalisation; results in significant disability or incapacity; requiring medical or surgical intervention to prevent any of the above; leads to foetal distress, foetal death or consists of a congenital anomaly or birth defect; or is otherwise considered medically significant by investigators. An adverse reaction (AR) is any untoward and unintended response to the psychological intervention or other study procedures. A suspected unexpected serious adverse reaction (SUSAR) is any AR that is judged to be both serious and unexpected.

All AEs will be recorded immediately but no later than 24 hours after first learning of the event/reaction on both the Adverse Event Report Form (Appendix A of Adverse Event SOP) and the adverse event spreadsheet. The adverse event/reaction will be discussed at the soonest possible instance with the supervisory team to determine severity, seriousness and relatedness to study procedures. All SAEs, SARs and SUSARs will be reported to the Sponsor immediately or no longer than 3 days after hearing about the event/reaction. All other reporting guidelines are outlined in the SOP.

All AEs will be reviewed every three months by AB in order to discern if there are any patterns in AE incidence. All AEs will be included on the annual report to the NHS REC.

12) PEER REVIEW

Drafts of the protocol have been reviewed with the supervisory team and internal reviewers in the Department of Psychology and Mental Health at the University of Manchester.

13) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee approval will be obtained before commencing research.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2 Risks

Participant Distress

It is possible that during the course of the research, participants may become distressed by talking about their voice hearing experiences. Participants' distress may present itself in several ways, including overtly (crying, fidgeting, etc.) or covertly (more hesitation when speaking, etc.).

During assessments, if a participant becomes distressed, they will be offered the opportunity to pause or stop the assessment. AB will follow the distress protocol outlined in Appendix 2 of the Safeguarding Protocol. The assessment will only continue if the participant feels comfortable to do so. If further safeguarding measures are required, the steps outlined in the Safeguarding Protocol will be followed.

Given the sensitive nature of the topics discussed in hearing voices groups, it is possible that participants may experience distress at some point during group participation. Participants will be assured that it is normal to feel distressed when discussing sensitive issues. If a participant becomes distressed during the group, they will be given the opportunity to either talk about that distress within the group, speak one-on-one with either the peer or clinically-qualified facilitator, or leave the group (either temporarily or permanently). In the case of the latter, one of the facilitators will follow up with the participant via phone call to mitigate any distress and address any potential safeguarding concerns. In all instances where distress arises, the distress policy will be adhered to.

Participant Risk of Harm to Self/Others

During the course of the research, a participant may disclose information that would indicate that they are at risk of harm to themselves/others. In this instance, the participant will be informed that the researcher or clinically-qualified co-facilitator (in cases where risk is disclosed during the hearing voices group) will need to break confidentiality and report

the risk, in the first instance, to the supervisory team. Information about breaking confidentiality is outlined in the PIS and CG and will be reiterated before each assessment and peer support group meeting.

To further mitigate participant risk of harm, the following procedure will be adhered to. Prior to commencing any study procedures, AB will collect the name and contact information of the care coordinator for those recruited from NHS trusts, and the name and contact information of the GP of participants recruited from voluntary/third-sector organisations and social media. AB will also collect the postcodes of all participants to ensure that emergency services are able to locate the participant quickly should an emergency arise.

All assessments and groups will take place online via videoconference. Participants will be advised that they can turn their camera off if they feel more comfortable doing so.

Prior to any interview or assessment, the following steps will be taken:

1) AB will familiarise herself with local support services/safeguarding teams and ensure that she has the contact information for the participant's care coordinator (for those recruited from NHS Trusts) or GP (for those recruited from voluntary/third-sector organisations or via social media).
2) AB will inform her supervisory team of the time and place of the assessment. This is to ensure that there is clinical cover at the time of the assessment and that the location is known. If no member of the supervisory team is available, another clinically trained researcher in the Division of Psychology and Mental Health will provide clinical cover.
3) AB will remind the participant that the assessment will be audio recorded.
4) AB will explain that all information disclosed during the course of the assessment will be kept confidential, except in cases where there is immediate risk of harm to the participant or others. In this instance, AB will inform her supervisory team and the care coordinator or GP of the participant.

5) Participants will be informed prior to the start of the assessment that they may stop or end the interview at any point and doing so will not jeopardise any care they are receiving.

When the assessment is finished, the following steps will be taken:

1) AB will debrief participants, including asking them how they are feeling and if they wish to discuss anything else.
2) Each participant will receive a debrief sheet, which contains contact information for the research team as well as information on helplines and support organisations.

Each participant will receive a debrief sheet, which contains contact information for the research team as well as information on helplines and support organisations.

Researcher Lone Working

All assessments will be conducted according to the Division of Psychology and Mental Health's Safe Lone Working Practices & Risk Assessment Guidelines. Although efforts will be made in the first instance to schedule assessments during working hours (Monday – Friday, 9am – 5pm), assessments will be scheduled at a time that is convenient for the participant. If the assessment takes place outside of working hours, and out-of-hours safety check contact will be named prior to the interview. All assessments and hearing voices group meetings will take place during normal working hours and will be conducted entirely remotely via videoconferencing platforms.

Data Protection and Confidentiality

Participants will be informed that their interview will be audio-recorded via the PIS and CF and this will again be verbally reiterated by AB prior to the interview commencing. All interviews will take place over Zoom or MS Teams, both of which are University-approved interview software. Interviews will be recorded using Zoom/MS Teams' built in recording feature. When interviews take place over Zoom, participants will be advised that Zoom automatically records both audio and video in separate files and that the video file will be permanently deleted immediately after the interview finishes. When interviews take place over MS Teams, participants will be advised that MS Teams automatically records one file

with both audio and visual data. As such, a video file of the interview will be retained until after transcription is complete. Participants will also be advised that they can have their camera off for the interview, however Zoom/MS Teams will still record their name and profile picture. Interview recordings will then immediately be transferred to the University of Manchester's Secure Research Data Management Storage (RDMS) and deleted from the original device. Recordings and transcripts will be pseudonymised. Once interviews have been transcribed, the recordings will be permanently deleted. Participants will be assured that recordings will be made of the interviews only, not of the hearing voices group meetings.

Hard copies of participant assessments will be stored in locked file cabinets in the Division of Psychology and Mental Health at UoM and will be accessible only to members of the research team. Electronic copies of participant assessment data will be stored on the RDMS. In accordance with the UoM's Information Governance Office Records Retention Schedule, all research data will be kept for a minimum default period of five years after publication.

Data will be stored in accordance with the General Data Protection Regulation (GDPR) and the Data Protection Act of 2018. Participants' confidentiality will be maintained by removing any identifying information from research material (e.g., names, locations) and assigning each participant a unique participant ID (i.e., P01, P02) which will be used throughout the study. Participant data will be stored on the UoM's secure RDMS. A participant ID key will be stored on the UoM P: Drive; a separate, secure system from the RDMS which enables identifiable information to be stored separately from all other participant data. The pseudonymisation key will be destroyed following completion of all study procedures and data analysis, at which point the data will be fully anonymised.

The only instance in which confidentiality will be broken is if there is a risk of harm to the participant or others. The participant will be informed of this on the PIS and CF and it will be reiterated by AB at the beginning of each assessment and group meeting. In such an instance, AB will inform the participant that confidentiality will need to be broken and then will notify the supervisory team at the earliest opportunity and follow the safeguarding and reporting guidelines in the Safeguarding Protocol.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

No external funding will be sought for this study.

16) PUBLICATION POLICY

AB and the Sponsor own the data generated from this study. Upon completion of data collection, AB will be in charge of analysing, synthesising and producing a final report of the data, under the guidance of the academic supervisors. The full study report and protocol will be accessible via the Sponsor's service within 12 months of the completion of the study. The research team retain the right to publish the study in peer-reviewed scientific journals, internal reports, and conference presentations. The role of the Sponsor will be acknowledged within individual publications.

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