Full title:	Managing Unusual Sensory Experiences in people with an At Risk Mental State for Psychosis (MUSE-ARMS)
Short title:	MUSE-ARMS
Protocol version:	**Version 2**
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SUMMARY

Title:	Managing Unusual Sensory Experience in people with an At Risk Mental State for psychosis (MUSE-ARMS)
Objectives:	To investigate the acceptability of a novel treatment manual for unusual sensory experiences.
Design:	A feasibility study to investigate the acceptability of a targeted treatment for unusual sensory experiences for people who show risk factors for psychosis. The intervention will be completed by a psychological therapist in 2-4 sessions, with baseline and post treatment assessment, including qualitative feedback from both the participant and therapist, for the 20 participants.
Treatment schedule:	All participants will receive a manualised treatment that includes subtyping of unusual sensory experiences and targeted psychoeducation and treatment. The treatment will take 2-4 sessions and will be conducted by a psychological therapist.
Proposed start point:	03/12/2018
Proposed end point:	**26/09/19 (last participant, last assessment)**
Study duration:	**10 months**

INTRODUCTION

Cognitive behavioural therapy (CBT) is recommended in current NICE guidelines for the treatment of psychosis. The recent NCAP audit (2018) suggests that only 26% of people with psychosis are offered CBTp. The evidence suggests that CBT has, at best, modest effects on the frequency and severity of psychotic symptoms (Jauhar, McKenna, Radua, Fung, Salvador, & Laws, 2014; Bighelli et al, 2018). This is also true when one focuses on the effect of CBT on auditory verbal hallucinations (or 'voice-hearing'; van der Gaag, Valmaggia, & Smit, 2014). However, existing research has treated voice-hearing as a uniform experience, despite evidence that many different types of voice-hearing may exist (McCarthy-Jones et al., 2014). It is possible that therapy for voice-hearing may be more effective when it is tailored to the type of voice-hearing a person experiences. Therefore, the challenge is both to increase the effectiveness and the availability of CBTp.

This possibility has been examined by the Chief Investigator (CI) in a small, case-series study (Robson, Freeston, Bruce, & Dodgson, under review). In that study, a novel treatment manual, which focussed on identifying the subtype of voice-hearing a service user was experiencing, and then tailored therapy to that subtype, was employed. Of the seven participants who took part in that study, four showed improvement in symptoms, and three showed no change in symptoms. That treatment manual has since been expanded, and has been adapted so that it can be delivered using a tablet computer (e.g., an iPad) during a therapy session. This is potentially valuable as it helps clinicians to demonstrate complicated ideas to service-users through the use of videos and other media. This version of the manual has since been used in routine services by a group of local clinicians.

A larger feasibility trail has just been completed with 13 out of 24 participants completing the intervention. During this feasibility trial, it became clear that individuals were more likely to complete and benefit from the treatment if they began the therapy relatively early in the course of psychosis. The treatment has been further developed, based on feedback from this trial. We are currently preparing a Stage Two funding bid for a Research for Patient Benefit (RfPB) grant to further this research in a First Episode of Psychosis (FEP) group, conducted by non psychological therapists.

The proposed research will move the intervention upstream into individuals with an At Risk Mental State for Psychosis (ARMS). This group is characterised by either 1) a brief episode of psychosis, lasting no more than 5 days, that remits without treatment, 2) a group who have attenuated symptoms of psychosis that do not meet the threshold for the diagnosis of psychosis and 3), a group that have a deterioration in functioning and a family history of psychosis (Yung et al., 2005). The proposed intervention would help people understand and manage hallucinations, with the aim of reducing the distress associated with the experience and the rates of conversion to full psychosis (typically 30% of people convert to psychosis within two years).

The proposed study, therefore, aims to investigate the acceptability (for clinicians and service-users) of this updated version of the treatment manual in an ARMS sample. This study will also allow us to investigate which variables should be used as primary outcomes in a full-scale trial, which we intend to run if the results of this study are promising. Although this research is

informed by previous research into the FEP group and the RfPB bid, this research is in an earlier stage of the research cycle. We believe that there are key differences between the clinical groups, for example that the FEP group are more likely to have developed delusional explanations for their unusual sensory experiences and also between the outcomes, for example in the ARMS group, a key outcome is preventing or delaying conversion to psychosis.

STUDY OBJECTIVES

Our main objective is to investigate the acceptability of a novel treatment manual for unusual sensory experiences or hallucinations. This manual has three novel aspects. First, it focuses on identifying the type of hallucination a service-user reports, and then attempts to tailor treatment to that type of hallucination. Second, the psychoeducation and coping strategies included in the manual are based on current theoretical models of hallucinations, and so are refinements of existing psychoeducation and coping strategies used in CBT for psychosis and related mental health problems (e.g., post-traumatic stress disorder). Third, the manual is delivered with the help of a tablet computer (e.g., an iPad). This allows clinicians to use prepared videos (and other types of media) to demonstrate psychological phenomena and to help service-users carry out behavioural experiments. This treatment approach has been found to be acceptable for people experiencing psychosis (Dodgson et al., in preparation), but we believe it may be helpful for people with an At Risk Mental State (ARMS) for psychosis. Our main objective is to investigate the acceptability of this treatment approach with an ARMS group.

Our secondary objective is to use this study as a way of identifying the most appropriate outcomes for a full-scale trial, which we intend to run if the results of this study are promising. This is important because we expect that the intervention will affect a number of different components of hallucinations, namely frequency, beliefs about hallucinations, degree of control, and distress.

OVERVIEW OF METHODOLOGY

This study will take a mixed-methods research approach to establish feasibility and acceptability of the MUSE toolkit in a group of service-users with an At-Risk Mental State for Psychosis, using a single-group design. Mixed-methods research combines qualitative and quantitative methods and offers a pragmatic way of collecting data that is rich, rounded, and nuanced, while also being directly comparable to findings in other research (Johnson & Onwuegbuzie, 2004; Creswell & Clark, 2011). 20 service-user participants with ARMS will receive assessments on their entrance into the study and after 6 weeks of treatment or 4 therapist sessions (whichever is later). The baseline assessment will include quantitative measures of current symptoms, mood, quality of life, and aims for therapy. The follow-up assessment will include all of the above again, plus quantitative measures of recovery and satisfaction with therapy, plus a short, structured interview designed to gather qualitative data on treatment acceptability.

In parallel, staff participants (the psychological therapists administering the treatment) will be asked to complete quantitative measures of treatment adherence after each service-user has completed a session. They will also be invited to take part in a similar structured interview, at the end of the study gauging their views on the treatment acceptability and feasibility.

Quantitative and qualitative data from each of these study strands will be combined as part of the data interpretation stage (a triangulation design) following a convergence model (Cresswell & Clark, 2011), i.e. the data will initially separately before being combined and compared to elicit points of agreement, contrast, and new questions to examine.

STUDY PROCEDURES

Inclusion criteria

Participants will:

1. Be in contact with Early Intervention in Psychosis services and accepted on the ARMS pathways following assessment by the Comprehensive Assessment of At Risk Mental state (CAARMS).

2. Have a history of hallucinations for at least six weeks or a recent history of brief but intense hallucinations.

3. Be aged 16 and above;

4. Consider their unusual sensory experiences (voices or visions) as a main presenting difficulty, and indicate that they would like to receive a psychological intervention specifically designed to address hallucinations;

5. Have the capacity to provide informed consent; and

6. Be judged by their clinician to be clinically stable for the preceding 4 weeks.

Exclusion criteria

Potential participants will not be eligible if:

1. The experience of hallucinations/psychosis has a strong biological basis (owing to traumatic brain injuries, organic psychoses, or dementia).

2. They have insufficient command of English to complete the research interviews and measures.

3. They have an intellectual disability, or severe cognitive dysfunction that might preclude their ability to provide informed consent, understand the study procedure and/or fully appreciate the potential consequences of their participation.

4. They have a primary diagnosis of substance misuse dependency.

5. They are identified by the care team as being too acutely unwell to participate in the research

Consenting procedures

Written informed consent will be obtained from each participant prior to any participation or study-specific procedures. Service-users will be invited to participate in the study by their care team. Service-users who express an interest in participating will be contacted by the Research Assistant who will be responsible for obtaining informed consent. Copies of the study consent forms and participant information sheets (PIS) are included in Appendix B.

Psychological Therapists have been approached through the PI Steph Common, who is the trustwide lead for Early Intervention in Psychosis services in TEWV NHS FT. They have been invited to participate if their core role includes seeing referrals for people in the ARMS group. Interested therapists will be issued with the agreed Staff Information Sheet (SIS), once a final version has been agreed. After at least 24 hours to consider the SIS, they will be asked to complete the final Staff consent form and will then be able to participate in the research.

Invitation to participate

Early Intervention in Psychosis services will identify people who may be eligible to participate and are appropriate for a psychological therapy. Potential participants will be identified by the care team either when the service-user is being referred to the psychological therapist or during routine assessment appointments with the psychological therapist. The procedures vary between teams about how people with an ARMS for psychosis are referred for a psychological therapy. The psychological therapist or another member of the care team will explain to potential participants that they are eligible to take part in a study being run in collaboration with Durham University, and that the study would involve them completing two assessments to see how their symptoms change over the course of treatment. The potential participant will be assured that their treatment will not be adversely affected if they decide not to participate. Service-users who show an initial interest in taking part in the study will have their contact details passed on to the study RAs. They will contact the participant, offer further information about the research and if they remain interested, send out the PIS and arrange to visit them to take consent.

Obtaining informed consent

The study RAs will contact potential participants by telephone to assess their interest in taking part. When appropriate, the study RAs will arrange a face-to-face appointment to discuss the study in more detail, and to obtain informed consent. During this appointment, the study RAs will explain the aims of the study, what participating will involve, as well as the risks and burdens associated with participating. In addition, it will be emphasized to the service-user that they are free to refuse any involvement with the study, that they would be able to withdraw their consent at any point during the study without having to explain their reason(s) for doing so, and that their treatment will not be adversely affected by them refusing to participate or by withdrawing their consent at a later date. This face-to-face appointment will typically take place within seven days of the telephone conversation and before the first therapy appointment with the psychological therapist, but service-users will always be given at least 24 hours from receiving the PIS to consider giving their consent for the study.

Study intervention

The intervention we will use is a novel treatment manual for hallucinations, which has been developed by the CI, in collaboration with the co-applicants and other clinicians. The treatment is divided into the following Modules:-

1. How the Mind Works. This module outlines current understanding of key psychological processes, such as threat detection, the importance of prediction (top down processing) and how intrusive thoughts work.

2. What are Voices? This module provides normalising information about the frequency of voices, the factors that tend to increase voice hearing (for example substance misuse and sleep deprivation) and gives testimonies from other voice hearers.

3. Assessment. This module encourages therapists to identify the subtype of hallucination a service-user is experiencing. For voice-hearing specifically, this is achieved by asking the voice-hearer about the content of the voice's utterances, the sensory characteristics of the voice, and the cognitive, emotional, and environmental triggers of the voice. After the assessment the therapist should be able to identify whether the voice hearing is an Inner Speech-Auditory verbal hallucination (IS-AVH), a Memory Based AVH (MB-AVH) or a Hypervigilance AVH (HV-AVH).

4. Inner Speech. This module provides psychoeducation about the evidence that suggests that voice hearing may be people not recognising their own inner speech. It outlines the conditions that make this more likely and the properties of inner speech that make voice hearing possible. An individual formulation of voice hearing experiences is co-produced and then targeted coping strategies and behavioural experiments are employed. The PowerPoint version of this module has been attached as additional information to provide a detailed example about the treatment.

5. Memory Based. This module provides psychoeducation about how memories from trauma are more likely to be experienced as intrusive memories, without contextual cues and can therefore be experienced as belonging to the here and now. An individual formulation of how the memory may be experienced as a voice is developed and then targeted coping strategies and behavioural experiments are employed.

6. Hypervigilance. This module provides psychoeducation about how our brain uses prediction to interpret the world and manage the amount of sensory data received. If people are expecting threatening stimuli they tend to scrutinise poor quality sensory data and therefore rely more heavily on predictions, whilst adopting a 'better safe than sorry' decision bias. These factors all make an individual more likely to have a false positive, of hearing the expected speech when it is absent. An individual formulation of how the hypervigilance hallucination occurred is developed and then targeted coping strategies and behavioural experiments are employed.

7. Seeing Visions. This module covers psychoeducation about how our perceptual system can easily be fooled, for example the strong use of predictions and has certain biases, for example searching for faces. An individual formulation is developed which identifies what it is about the experiences that is most distressing (content, persistence or meaning of having the vision). A treatment plan is then develops that normalises the experience and tried to address the key cause of distress.

8. Sleep. This module tries to provide psychoeducation and treatment strategies about sleep, which is often a key factor in the development and maintenance of all types of unusual sensory experiences.

The psychoeducation materials, behavioural experiments, and coping strategies included in the manual are refinements of existing psychoeducation, behavioural experiments, and coping strategies used in CBT for psychosis and related mental health problems (e.g., post-traumatic stress disorder, reducing arousal). Therapists will not, therefore, be required to learn an extensive set of new techniques. Rather, the manual tries to guide therapists to tailor existing therapeutic approaches to the needs of the voice-hearer, based on a more powerful explanation of their experiences (formulation) and matching approaches to specific subtypes.

Schedule of intervention

Psychological therapists will be asked to use the manual in 2-4 of the initial therapy sessions with participants. The number of sessions is based on previous work with other groups, but clinician can choose to use the manual for more sessions, if they deem necessary. This design will ensure that participants receive adequate exposure to the manual in therapy sessions for us to determine its acceptability, but also allows clinicians freedom to address problems that the manual is not intended to address (e.g., relationship difficulties) after they have worked on hallucinations.

Schedule of assessments

After providing informed consent, participants will complete the baseline assessment. Assessments will measure various aspects of their experiences of hallucinations (e.g., frequency, distress, location, disruption to life), participants' beliefs about their hallucinations (e.g., to what extent voices are powerful), as well as mood problems, quality of life, and perception of therapeutic alliance (see Study Assessments below). The second assessment will take place after the participant has completed the intervention on hallucinations and before any further psychological therapy begins. It is estimated that the first assessment will last 1.25 hours, while the second assessments will be 2 hours long.

Assessments and interviews will take place at participants' homes or NHS premises, depending on a participant's preference. The lone working policy of TEWV CRN will be followed when the research is undertaken at a participants' home

Study assessments

The following primary and secondary outcome assessments and treatment acceptability measures will be included in the study.

Service-user participant measures:

Potential primary outcome assessments

The Psychotic Symptom Rating Scales (PSYRATS; Haddock, McCarron, Tarrier, & Faragher, 1999)

This is a clinician administered semi-structured interview of hallucinations (including questions about frequency and intensity of distress). This measure will be used in both assessment sessions.

The Comprehensive Assessment of At-Risk Mental States (CAARMS; Yung et al., 2005)
This is a semi-structured interview that will be used to assess psychotic symptoms in both sessions. To shorten the assessment interview, only the perceptual abnormalities subscale will be used in the first interview.

Potential secondary outcome assessments

The short Depression, Anxiety and Stress Scales (DASS-21; Lovibond & Lovibond, 1995)

The questionnaire assesses emotional distress, including symptoms of anxiety and depression. This measure will be administered during both sessions.

Investigating Choice Experiments Capability Measure for Adults (ICECAP-A; Flynn et al., 2015). This measure will be used to assess the emotional and mental aspects of quality of life at both sessions.

The Questionnaire about the Process of Recovery (QPR; Neil et al., 2009).

Subjective recovery in intrapersonal functioning and interpersonal functioning will be assessed at the follow-up from the study.

Treatment acceptability

The CHoice of Outcome In CBT for psychosEs (CHOICE; Greenwood et al., 2010)
This service—user-led measure will be used to evaluate outcomes of CBT for psychosis and assess therapy-related goals during both sessions.

Satisfaction with Therapy and Therapist Scale (STTS; Oei & Shuttlewood, 1999)
This short scale will be used to assess the overall acceptability of the therapeutic intervention at the study follow-up only.

Structured Interview

We will conduct an acceptability, structured interview with participants at the end of the intervention. This interview will cover several topics (see Appendix A), including whether the service-user would have been prepared to be randomised into a TAU arm, if they found the tablet format helpful, whether they found that the tablet hindered the development of a therapeutic alliance with the therapist, how helpful being presented with an scientific explanation of unusual sensory experiences was and if there was anything unhelpful about the intervention.

Staff participant measures

Adherence Checklist

We will take a copy of the formulation the clinician and service-user developed during therapy after the participants have completed the treatment. After each session, therapists will record which modules they used from the treatment. These steps will be taken so that we can investigate how the use of the study intervention influences the formulations clinicians and

service-users develop, and so that we can assess to what extent clinicians have followed the manual in therapy, as well as how often they used the manual.

Structured Interview

We will conduct an acceptability, structured interview with staff participants at the end of the intervention. This interview will cover similar topics to the service users structured interview. We will ask whether they found the tablet format helpful, whether they found the tablet hindered the development of a therapeutic alliance with the service user, how effective they found the tablet in presenting complex ideas that explained the onset of unusual sensory experiences, and if there was anything unhelpful about the intervention. The therapists will also be asked about any potential improvements or additions to the tablet, so we can continue to try to improve the intervention.

The RAs will require training in completing the CAARMS and PSYRATS. We will provide supervision to the RAs on qualitative methodology to ensure that the structured interview is not biased.

Copies of the PSYRATS, CAARMS, DAS-21, CHOICE, QPR, ICECAP-A, Satisfaction with Therapy and Therapist Scale, and the acceptability structured interviews, are included in Appendix A.

Participant withdrawal

Participants will withdraw from the study if they withdraw their consent to continue. There are no specific criteria for premature withdrawal. If participants wish to withdraw from the study, they may do so at any time. We will ask for their consent to retain the data that they have already provided during their involvement in the study.

End of study definition

The study will finish after the final assessment with the final participant is completed.

STATISTICAL CONSIDERATIONS

Considerations about sample size were largely influenced by pragmatic concerns, rather than issues of statistical power, since investigating whether there is a statistically significant effect of the novel intervention is not the primary aim of the study. The decision to aim to recruit a sample of 20 participants was, instead, based on what would be reasonable to expect in terms of participant recruitment, and on what is the norm for studies that evaluate the acceptability of psychological therapies.

We will calculate change scores for any of the quantitative measures used across assessments 1 and 2. These will be used to inform the overall interpretation of participants' experience of therapy (combining qualitative and quantitative data). We are also interested in understanding which areas of the participant's life the intervention may impact upon, for example, distress linked to voice hearing, interpersonal functioning etc.

Qualitative data, gathered from the structured interviews with patients and staff, will be analysed using an inductive thematic analysis (Braun and Clarke, 2006). This form of analysis allows for both basic and more complex themes to be classified from interview data (based on

categorising sections of transcripts), based on the data themselves rather than a prior theory (Patton, 1990). It has been used successfully by members of the research team on previous research relating to hearing voices (Woods et al., 2015; Alderson-Day et al., 2017) and in supervision of MSc dissertation projects at Durham University. The study RAs will complete this analysis under the supervision of Dr Ben Alderson-Day and other members of the "Hearing the Voice" team, who possess a range of expertise in interdisciplinary research and methods. Although typically unstructured or semi-structured interviews would ideally be used for qualitative work of this kind, we have chosen structured interviews to allow for junior RAs to more readily conduct the interviews and gather valuable data for later re-analysis, under supervision. Because the interviews will be audio recorded and fully transcribed, these data will also be available for later re-analysis should further work be required to establish emergent themes in the data. With this in mind, Hearing the Voice plan to employ a new postdoctoral social scientist with expertise in qualitative interviewing and coding. This person will be in post in the New Year and be available to support analysis towards the end of the study timeline.

ETHICAL CONSIDERATIONS

The proposed study will be conducted in accordance with the principles of the Declaration of Helsinki (WHO, 2000) and with the principles of Good Clinical Practice. The proposed study raises a number of specific ethical issues. One concern is that the relationship between service-users and their clinician, who will be the first person to discuss the study, will have undue influence over the service-users' decisions about whether or not to participate. However, we feel we have taken reasonable steps to avoid this. While clinicians will inform clients about the study, and will ask whether they are interested in hearing more about the research, clinicians will not be involved in the consent process beyond that point. The study RAs, who are not involved in the clinical care of any potential participants, will perform consenting procedures, which will reduce any influence of service-users' clinicians.

Another issue relating to obtaining informed consent from participants is that we have adopted an 'opt out' rather than an 'opt in' consenting procedure. That is, the study RAs will contact potential participants to ask whether they are interested in taking part in the study, rather than waiting for potential participants to contact them. This is not an ideal situation, but, on balance, seems the most appropriate option for the proposed study. We discussed this issue with a group of service-users, who supported the recruitment method we propose to use. They noted that people with mental health problems often have 'lots on their mind' (especially if they are only beginning therapy sessions) and so frequently forget to perform some tasks. Thus, it is quite likely that even when a potential participant is keen to take part in the study, they might forget to contact the research team about this. Some of the service-users we have spoken to now work on psychosis research projects for the NHS. They reported that, in one recent study, where potential research participants were asked about how they would like to find out more information about the study, all asked for the research team to contact them. The recruitment procedure we propose to use does, therefore, seem appropriate in this instance.

For participants, a small set of burdens and of risks will be associated with taking part in the proposed study. There is the risk that participants will be exposed to an ineffective or dangerous therapy. However, this risk can be considered to be small for two reasons. First, the novel treatment manual does not involve any novel therapeutic techniques. It simply tries to tailor existing therapeutic techniques, which clinicians are typically familiar with, to the type of voice-

hearing or hallucinations that service-users report. At worst, therefore, participants will receive therapy that spends longer examining the factors (e.g., emotions, situations) that trigger their hallucinations and the nature of their hallucinations (e.g., addressing questions about their content, such as whether or not it is repetitive). While this may prove distressing for some service-users (e.g., some voice-hearers find discussion of the content of their voices very upsetting), this distress will be manageable within a clinical setting. Second, a feasibility study (Dodgson et al., in preparation) which examined the use of the novel treatment manual in thirteen participants, found no evidence to suggest that the novel manual was harmful.

Another risk for participants who take part in the proposed study is that discussing their experiences during symptom and functioning assessments may be distressing. These assessments are unavoidable, and so this risk has to be accepted. However, we have taken care not to minimise assessment sessions, for example selecting the short forms of some measures. In addition, participants will be reminded at each assessment, that they can halt their participation (or simply rearrange an assessment session) if they are feeling distressed.

Accessing the formulation that service-users and clinicians develop during therapy raises several ethical issues, as this document could contain very sensitive information about service-users' lives (e.g., incidents where they have been the victim of abuse). It could be argued, therefore, that it is inappropriate for the research team to have access to this document. However, given the importance of formulation in psychological therapy, it will be extremely useful for us to compare (e.g., in terms of whether the idea of sub-typing is present in the formulation) the formulations developed in the two arms of the study. It is also important to note that participants can refuse to share the formulation with the research team when they provide consent. At assessment two, participants who originally consented to the research team having access to the formulation will be reminded that they did so, and will be offered the chance to withdraw that consent. Thus, any participants who do not wish to share sensitive information that may be present in their formulation will be under no pressure to do so.

Another ethical issue relates to the confidentiality of data. A number of steps will be taken to ensure confidentiality. All data collected in the proposed study will be pseudo-anonymised. Consent forms, which could provide information that would compromise pseudo-anonymity, will be stored in a locked filing cabinet in a locked office in a secure building at Durham University. Paper versions of data will be stored in a locked filing cabinet in a separate locked office in the same secure building at Durham University. Electronic data will be stored in password protected files, on password-protected university computers at Durham University. The Hearing the Voice project are experienced at data management and having well established systems and processes, therefore the decision was taken that they would provide the most secure site.

One burden for participants who take part in the proposed study will be the time taken to obtain informed consent, to complete psychological and functioning assessments, and to complete debriefing. In sum, these non-clinical interventions will take around three hours. To try to minimise this burden, we have been careful not to plan very lengthy assessments, and have tried to keep to a (reasonable) minimum the number of symptom and functioning assessments participants are asked to complete. We have also made it clear in the Participant Information Sheet (and will make it clear when obtaining informed consent) the time burden involved in participating in the proposed study.

Finally, at the end of the proposed study, the intervention will remain available to clinicians who have delivered it as part of the study (and who are typically already using the manual in routine care).

SAFETY CONSIDERATIONS

It is possible that participating in the proposed study will elicit psychological distress in some participants (e.g., participants may become distressed when discussing their voice-hearing with the researchers, or when discussing triggers of their voice-hearing during therapy sessions). A number of measures are in place to protect the safety of participants. The study RAs who will be conducting assessments have experience of conducting potentially distressing research with vulnerable groups, and throughout the study, all participants will remain in the care of their normal clinical teams.

DATA HANDLING AND SECURITY

Electronic research data collected during the proposed research will be stored on password-protected files, on password-protected computers and will be accessible only to the co-applicants. Manual (i.e., paper) data will be stored in locked filing cabinets in locked offices at Durham University. All data will be pseuonymised, with access to consent forms the only means of breaching pseudonymity. Consent forms will be stored in locked filing cabinets in locked offices at Durham University. Consent forms and manual data will be stored in separate offices. Results reported in publications will deal only with aggregated data and will not include personally identifiable information. Data will be handled in accordance with the General Data Protection Regulation, the NHS Caldicott Principles, and the Research Governance Framework for Health and Social Care (2005). Data will be held for 5 years, in line with the Research Governance Framework, and will be stored in secure archiving at Durham University. The Hearing the Voice project have considerable experience at data management and have secure rooms to minimise any risk of a data breach.

FINANCE AND FUNDING

Funding for the proposed research comes primarily from a Wellcome Trust Collaborative Award to some of the co-applicants (GD, CF, BAD). Funding for the RAs time comes from PI and Greenshoots funding awarded to two of the applicants (SC and GD).

INDEMNITY

Northumberland, Tyne and Wear NHS Foundation Trust has agreed to act as the sponsor for this research. Indemnity is, therefore, provided through NHS schemes. Guy Dodgson, the CI, is an NHS employee, and the NHS indemnity scheme applies in his case. The study RAs are also employed by the NHS, and the NHS indemnity scheme applies in their cases. Two of the co-applicants (Charles Fernyhough and Ben Alderson-Day) are employed by Durham University. Durham University has in force a policy providing legal liability cover and the activities are included within that coverage for Durham University's involvement in this study.

DISSEMINATION OF RESEARCH FINDINGS

Research findings will be published by the co-applicants. In line with the funding body's policy, all research papers will be published in open access formats. In addition, research findings will be disseminated through blog posts, podcasts, and research seminars.

APPENDIX A – CONTENTS

Structured Interview Topic – Service-User participants

Thank you for agreeing to answer some questions about your experience of the therapy. We want to understand how people found the approach and if there was anything that you would suggest we change. We want to record the interview so we can see if any themes emerge about the treatment and might also use some anonymous quotes from people in the next stage of the research. You are welcome to say as much or as little as you like to each question, or not answer at all. Are you ready for us to begin? (**RA switches on the recorder**)

My first questions are about the sessions you did with the therapist involving the smart tablet….

1. What was the intervention like for you?

2. How was it using the computer tablet?

3. Were there any particular things about the session that were helpful for you?

4. Were there any particular things about the session that were unhelpful for you?

5. Is there anything you would change about it?

6. Did it help you make sense of any of the unusual experiences you have?

7. Do you think the tablet made it influenced how easy it was to form a strong working relationship with your therapist?

8. Would you recommend the intervention to someone else with similar experiences?

My next questions are more about taking part in the research

.

1. When you started the study, we asked you to tell us about some of your experiences in an interview, and to fill out some questionnaires. What was that like for you? Is there anything you think should be done differently?

2. In our future research, we might need to run studies where people get “randomised” at the start – so some people would get to use the tablet, and some people wouldn’t. How would you feel about this?

3. If you were in a trial where you might randomly get placed in a part of the research where you get treatment as usual, or the new treatment, would you have agreed to participate?

4. Are there any other comments you would like to make about the research?

Structured Interview Topic – Staff participants

Thank you for agreeing to answer some questions about your experience of the therapy. We want to understand how people found the approach and if there was anything that you would suggest we change. We want to record the interview so we can see if any themes emerge about the treatment and might also use some anonymous quotes from people in the next stage of the research. You are welcome to say as much or as little as you like to each question, or not answer at all. Are you ready for us to begin? (**RA switches on the recorder**)

My first questions are about the sessions you did with the service user involving the smart tablet….].

1. What was the intervention like for you?

2. How was it using the computer tablet?

3. Were the tablets easy to use in the sessions?

4. Were there any particular things about the session that were helpful for you?

5. Were there any particular things about the session that were unhelpful for you?

6. Is there anything you would change about it?

7. Did it help you make it easier to build a formulation of the service users unusual experiences?

8. Do you think the tablet made it influenced how easy it was to form a strong working relationship with your therapist?

9. Would you recommend the intervention to another therapist?

My next questions are more about taking part in the research

.

1. Did the research procedure run smoothly? Would you suggest making any changes to it?

2. In our future research, we might need to run studies where people get “randomised” at the start – so some people would get to use the tablet, and some people wouldn’t. How would you feel about this?

3. If you participated in the next stage of the research and were asked to be a treatment as usual therapist, do you think you would be able to stop yourself using the ideas from the treatment?

4. Are there any other comments you would like to make about the research?

Adherence Checklist For

(Please tick topic used in any session)

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
1. **What are voices?**							
What are voices?							
How many people hear voices?							
Why does it become a problem?							
Can things get better?							
Personal experiences							
2. **How the mind works?**							
Thoughts and senses							
How thoughts work							
Embarrassing thoughts							
The power of attention							
How we use expectation							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
3. **Assessment**							
Types of unusual sensory experiences.							
What kind of voices do we hear?							
4. **Inner Speech**							
What is inner speech?							
Our inner speech can do amazing things							
Why do people not recognise voices?							
Thoughts are hard to control							
Blocking the loop							
Inner speech – what is the evidence?							
Tracking the self – Was that me?							
Writers and voice hearing							
Imaginary friends							
Formulation							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Voices and Relationships							
Transforming the voice							
Testing out your explanations							
Living well with voices							
5. **Memory Based Voices**							
Memory, dissociation, trauma							
The importance of trauma							
Threat system and Soothing system							
Formulation							
Treating trauma							
6. **Hypervigilance**							
Nature versus Nurture							
Filling in the gaps							
What our perception system is designed to do							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Response to danger							
Formulation							
Threat system and soothing system							
Mistrust							
7. **Seeing Visions**							
Is seeing believing?							
What do your visions mean to you?							
Perception system design							
Filling in the gaps							
Tracking the self – was that me?							
Imaginary friends							
Testing distressing appraisals							
Changing images							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Living well with visual experiences							
Voices, visions and relationships							
Challenging unacceptability							
Testing out your explanations							
Living well with voices and visions							
8. **Sleep**							
Why do we sleep?							

The Psychotic Symptom Rating Scales

Interview Schedule

Gillian Haddock Version 2009

AUDITORY HALLUCINATIONS

1. Frequency

Probing questions

How often have you heard your voices over the last week?

Thinking about the last week, what has it been like?'' e.g. every day, all day long etc"

Scoring criteria:

0 Voices not present or present less than once a week (specify frequency if present) 1 Voices occur for at least once a week 2 Voices occur at least once a day 3 Voices occur at least once an hour 4 Voices occur continuously or almost continuously i.e., stop for only a few seconds or minutes

2. Duration

Probing questions

When you have heard your voices over the last week, how long have they lasted?

Have they lasted for a few seconds, minutes, hours, all day long for example....?"

Scoring criteria:

0 Voices not present 1 Voices last for a few seconds, fleeting voices 2 Voices last for several minutes 3 Voices last for at least one hour 4 Voices last for hours at a time

3. Location

Probing questions

When you have heard your voices over the last week, where did they sound like they were happening?

Did they sound like they were inside your head and/or outside your head? Whereabouts do your voices sound like they are coming from?

Scoring criteria:

0 No voices present 1 Voices sound like they are inside head only 2 Voices outside the head, but close to ears or head. Voices inside the head may also be present. 3 Voices sound like they are inside or close to ears and outside head away from ears 4 Voices sound like they are from outside the head only

4. Loudness

Probing questions

How loud are your voices? Are they louder than my voice, about the same loudness, quieter or just a whisper?

Scoring criteria:

0 Voices not present 1 Quieter than own voice, whispers. 2 About same loudness as own voice 3 Louder than own voice 4 Extremely loud, shouting

5. Beliefs regarding the origin of voices

Probing questions

What do you think has caused your voices?

Are the voices caused by factors related to you, or due to other people or factors?

Are your voice caused by your mental health problems or illness?

How much do you believe that your voices are caused by (add interviewee's contribution) on an scale from 0-100 with 100 being that you are totally convinced, have no doubts and 0 being that it is completely untrue?

Scoring criteria:

0 Voices not present 1 Believes voices to be solely internally generated and related to self 2 Holds a less than 50% conviction that voices originate from external causes 3 Holds 50% or more conviction (but less than 100%) that voices originate from external causes 4 Believes voices are solely due to external causes (100% conviction)

6. Amount of negative content of voices

Probing questions

Do you think that your voices have said unpleasant things or negative things over the last week?

How much of the time do the voices say these types of unpleasant or negative items?

Scoring criteria:

0 No unpleasant content 1 Occasional unpleasant content 2 Minority of voice content is unpleasant or negative (less than 50%) 3 Majority of voice content is unpleasant or negative (50% or more) 4 All of voice content is unpleasant or negative

7. Degree of negative content

Probing questions

Can you tell me a bit about what you have heard your voices saying over the last week?

Can you give me some examples of the things you have heard this week?

Scoring criteria:

0 Not unpleasant or negative 1 Some degree of negative content, but not personal comments relating to self or family e.g. swear words or comments not directed to self, e.g. “the milkman’s ugly” 2 Personal verbal abuse, comments on behaviour e.g. “shouldn’t do that or say that” 3 Personal verbal abuse relating to self-concept e.g. “you’re lazy, ugly, mad, perverted” 4 Personal threats to self e.g. threats to harm self or family, extreme instructions or commands to harm self or others and personal verbal abuse as in (3)

8. Amount of distress

Probing questions

Have you found your voices to be distressing over the last week?

How much of the time have they caused you distress over the last week?

Scoring criteria:

0 Voices not distressing at all 1 Voices occasionally distressing, majority not distressing (<10%) 2 Minority of voices distressing (<50%) 3 Majority of voices distressing, minority not distressing (≥ 50%) 4 Voices always distressing

9. Intensity of distress

Probing questions

Over the last week when your voices have been distressing, how distressing has that been?

Thinking about the worst distress you could feel, over the last week, how have your voices compared to that? For example, has it been slightly, moderately distressing etc?

Scoring criteria:

0 Voices not distressing at all 1 Voices slightly distressing 2 Voices are distressing to a moderate degree 3 Voices are very distressing, although interviewee could feel worse 4 Voices are extremely distressing, feel the worst he/she could possibly feel

10. Disruption to life caused by voices

Probing questions

How much disruption have the voices caused to your life over the last week?

Can you tell me how the voices stopped you from working or doing any other daytime activity that you wanted to do?

How much have they interfered with your relationships with friends and/or family?

How much have they prevented you from looking after yourself, e.g. bathing, changing clothes, etc.?

Scoring criteria: 0 No disruption to life, able to maintain social and family relationships (if present)

1 Voices cause minimal amount of disruption to life e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support.

2 Voices cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The interviewee is not in hospital although may live in supported accommodation or receive additional help with daily living skills.

3 Voices cause severe disruption to life so that hospitalisation is usually necessary. The interviewee is able to maintain some daily activities, selfcare and relationships whilst in hospital. The interviewee may also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships. 4 Voices cause complete disruption of daily life requiring hospitalisation. The interviewee is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.

11. Controllability of voices

Probing questions

What control had you had over your voices over the last week?

How much control have you had over your voices when they happened over the last week?

Can you get rid of, dismiss or bring on your voices?”

Scoring criteria:

0 Interviewee believes they can have control over the voices and can always bring on or dismiss them at will

1 Interviewee believes they can have some control over the voices on the majority of occasions

2 Interviewee believes they can have some control over their voices approximately half of the time

3 Interviewee believes they can have some control over their voices but only occasionally. The majority of the time the interviewee experiences voices which are uncontrollable

4 Interviewee has no control over when the voices occur and cannot dismiss or bring them on at all.

Optional items

(i) Number of voices

How many voices do you experience?

(ii) Form of each voice

How does each voice refer to you? Does it say things that start with ‘you’, or ‘he/she’ or ‘I’?(1st person, 2nd person, 3rd person etc.)

(iii) Sex of voices

Are the voices males or female? How many voices are male and how many are female?

DELUSIONAL BELIEFS

1. Amount of preoccupation with delusions

Probing questions

Over the last week, how much time have you spent thinking about your beliefs about ……[insert client’s beliefs] ?

Scoring criteria:

0 No delusions, or delusions which the interviewee thinks about less than once a week. 1 Interviewee thinks about beliefs at least once a week. 2 Interviewee thinks about beliefs at least once a day. 3 Interviewee thinks about beliefs at least once an hour. 4 Interviewee thinks about delusions continuously or almost continuously.

2. Duration of preoccupation with delusions

Probing questions

When you have thought about any of your beliefs (i.e. [insert interviewee’s beliefs]…) over the last week, how long do they tend to stay in your mind? - Few seconds/minutes/hours, etc.?

Scoring criteria:

0 No delusions 1 Thoughts about beliefs last for a few seconds, fleeting thoughts 2 Thoughts about delusions last for several minutes 3 Thoughts about delusions last for at least one hour 4 Thoughts about delusions usually last for hours at a time

3. Conviction

Probing questions

At the moment, do you have any doubts about any of your beliefs, for example do you sometimes wonder whether they are real or not? (Go through each belief in turn).

How much do you believe in,,,[insert belief/beliefs]? Can you estimate this on a scale from 0 – 100, where 100 means that you are totally convinced by your beliefs and 0 being that you are not convinced at all?

Scoring criteria:
0 No conviction at all 1 Very little conviction in reality of beliefs, less than 10% 2 Some doubts relating to conviction in beliefs, between 10-49% 3 Conviction in belief is very strong, between 50 – 99% 4 Conviction is 100%

4. Amount of Distress

Probing questions

Have your beliefs about [insert interviewee's beliefs] caused you distress over the last week? How much of the time have they caused you distress over the last week?

Scoring criteria:

0 Beliefs never cause distress 1 Beliefs cause distress on the minority of occasions. 2 Beliefs cause distress on less than 50 % of occasions 3 Beliefs cause distress on the majority of occasions when they occur between 51-99% of time

4 Beliefs always cause distress when they occur

5. Intensity of Distress

Probing questions

Over the last week, when you have felt distressed by your beliefs about [insert interviewee's beliefs] how severe does this feel?" Have you felt slightly, distressed, moderately distressed etc.

Scoring criteria:

0 No distress 1 Beliefs cause slight distress 2 Beliefs cause moderate distress 3 Beliefs cause marked distress 4 Beliefs cause extreme distress, couldn't be worse

6. Disruption to life caused by beliefs

Probing questions

In what way have your beliefs caused disruption for you over the last week?

In what way have they stopped you working or carrying out a day-time activity?

In what way have they interfered with your relationships with family or friends?

In what way have they interfered with your ability to look after yourself, e.g. washing, changing clothes, etc.?

Scoring criteria:

0 No disruption to life, able to maintain independent living with no problems in daily living skills. Able to maintain social and family relationships (if present) 1 Beliefs cause minimal amount of disruption to life, e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support. 2 Beliefs cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The interviewee is not in hospital although may live in supported accommodation or receive additional help with daily living skills.

3 Beliefs cause severe disruption to life so that hospitalisation is usually necessary. The interviewee is able to maintain some daily activities, self-care and relationships whilst in hospital. The interviewee may also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships.

4 Beliefs cause complete disruption of daily life requiring hospitalisation. The interviewee is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.

Optional items

(i) Number of beliefs

Record the number of beliefs considered in the interview, use further probing questions if necessary

(ii) Content of each belief

Record the content of each belief considered in the interview, use further probing questions if necessary.

(iii) Conviction in each belief

It may be useful to record the conviction that the individual has in each of their beliefs that have been considered during the interview.

DASS21 Name: Date:

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all 1 Applied to me to some degree, or some of the time 2 Applied to me to a considerable degree or a good part of time 3 Applied to me very much or most of the time

1 (s) I found it hard to wind down 0 1 2 3
2 (a) I was aware of dryness of my mouth 0 1 2 3
3 (d) I couldn't seem to experience any positive feeling at all 0 1 2 3
4 (a)
I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)
0 1 2 3
5 (d) I found it difficult to work up the initiative to do things 0 1 2 3
6 (s) I tended to over-react to situations 0 1 2 3
7 (a) I experienced trembling (e.g. in the hands) 0 1 2 3
8 (s) I felt that I was using a lot of nervous energy 0 1 2 3
9 (a)
I was worried about situations in which I might panic and make a fool of myself
0 1 2 3
10 (d) I felt that I had nothing to look forward to 0 1 2 3
11 (s) I found myself getting agitated 0 1 2 3
12 (s) I found it difficult to relax 0 1 2 3
13 (d) I felt down-hearted and blue 0 1 2 3
14 (s)
I was intolerant of anything that kept me from getting on with what I was doing
0 1 2 3
15 (a) I felt I was close to panic 0 1 2 3
16 (d) I was unable to become enthusiastic about anything 0 1 2 3
17 (d) I felt I wasn't worth much as a person 0 1 2 3
18 (s) I felt that I was rather touchy 0 1 2 3
19 (a)
I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)
0 1 2 3
20 (a) I felt scared without any good reason 0 1 2 3
21 (d) I felt that life was meaningless 0 1 2 3
DASS-21 Scoring Instructions

The DASS-21 should not be used to replace a face to face clinical interview. If you are experiencing significant emotional difficulties you should contact your GP for a referral to a qualified professional.

Depression, Anxiety and Stress Scale - 21 Items (DASS-21)

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) is a set of three self-report scales designed to measure the emotional states of depression, anxiety and stress.

Each of the three DASS-21 scales contains 7 items, divided into subscales with similar content. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest / involvement, anhedonia and inertia. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress scale is sensitive to levels of chronic nonspecific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset / agitated, irritable / over-reactive and impatient. Scores for depression, anxiety and stress are calculated by summing the scores for the relevant items.

The DASS-21 is based on a dimensional rather than a categorical conception of psychological disorder. The assumption on which the DASS-21 development was based (and which was confirmed by the research data) is that the differences between the depression, anxiety and the stress experienced by normal subjects and clinical populations are essentially differences of degree. The DASS-21 therefore has no direct implications for the allocation of patients to discrete diagnostic categories postulated in classificatory systems such as the DSM and ICD.

Recommended cut-off scores for conventional severity labels (normal, moderate, severe) are as follows:

NB Scores on the DASS-21 will need to be multiplied by 2 to calculate the final score.

	Depression	Anxiety	Stress
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely Severe	28+	20+	34+

Lovibond, S.H. & Lovibond, P.F. (1995). Manual for the Depression Anxiety & Stress Scales. (2nd Ed.)Sydney: Psychology Foundation

COMPREHENSIVE ASSESSMENT OF AT RISK MENTAL STATES

(CAARMS)

BRIEF VERSION FOR USE IN EDIT

2015

A. Yung, L. Phillips, M.B. Simmons, J. Ward, K. Thompson, P. French, P. McGorry

THE PACE CLINIC
University of Melbourne,

Department of Psychiatry

Melbourne, Australia

Client Initials:	Client ID:
Date:	Rater(s):

OVERVIEW OF THE CAARMS

Aims:

- *To determine if an individual meets the criteria for an 'At Risk Mental State'.*
- To rule out, or confirm criteria for acute psychosis.
- To map a range of psychopathology and functioning factors, over time in young people at ultra high-risk of psychosis.

Structure of the CAARMS:

- Ratings are made on a range of subscales that target different areas of psychopathology and functioning. From these ratings it is then possible to extract information relating to the above aims.

Overview of Symptoms and Functioning - Longitudinal Change:

- At the first interview (not follow-up interviews), the CAARMS aims to obtain a general overview of the history of change from the premorbid state in the respondent. All available information should be used.
- Record the **time of first noted change** - date and age of respondent in years:

  Date: ……

  Age: ……

- Note first ever symptoms or signs:
  ……

  ……

  ……

  ……

  ……

- Overview of course since then - map on timeline e.g.:

First change Worst ever

Present state

Time

- Current time line:

First change Worst ever

Present state

Time

- **Family history of psychosis** in first degree relative?

  YES NO

- **If yes, please state who**
  ……
  ……

- **Use of medication (current or past)?**
  ……
  ……
  ……

NOTE: For the BLIPS group, the ONSET and OFFSET dates need to be recorded for each episode (not very first onset date and very last offset date), as to qualify under BLIPS criteria, symptoms cannot last more than a week at a time

Helpful prompt questions:

- How often does it happen?
- When did it last happen?
- Does it stop you from doing anything?
- When was it at its worst?
- What was it like at the worst point?
- What do your friends and family say about it?
- How distressed were you?
- How long does it last?
- Do other people see it the same way?
- Can you give me a specific example of that?
- Has it changed you behaviour in any other way?

1: POSITIVE SYMPTOMS

1.1 UNUSUAL THOUGHT CONTENT

Delusional Mood and Perplexity ('Non Crystallized Ideas')

- Have you had the feeling that something odd is going on that you can't explain? What is it like?
- Do you feel puzzled by anything? Do familiar surroundings feel strange?
- Do you feel that you have changed in some way?
- Do you feel that others, or the world, have changed in some way?

Bizarre Ideas ('Crystallized Ideas')

- *Made thoughts, feelings, impulses: Have you felt that someone, or something, outside yourself has been controlling your thoughts, feelings, actions or urges? Have you had feelings or impulses that don't seem to come from yourself?*
- Somatic Passivity: Do you get any strange sensations in your body? Do you know what causes them? Could it be due to other people or forces outside yourself?
- *Thought Insertion: Have you felt that ideas or thoughts that are not your own have been put into your head? How do you know they are not your own? Where do they come from?*
- *Thought Withdrawal: Have you ever felt that ideas or thoughts are being taken out of your head? How does that happen?*
- *Thought Broadcasting: Are your thoughts broadcast so that other people know what you are thinking?*
- *Thoughts Being Read: Can other people read your mind?*

Ideas of Reference (NOT in relation to suspiciousness and persecutory ideas)

- Ideas of Reference: Have you felt that things that were happening around you had a special meaning, or that people were trying to give you messages? What is it like? How did it start?

UNUSUAL THOUGHT CONTENT- GLOBAL RATING SCALE

0 Never, Absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Severe	6 Psychotic & severe
No unusual thought content.	**Mild elaboration of conventional beliefs as held by a proportion of the population**	**Vague sense that something is different, or not quite right with the world, a sense that things have changed but not able to be clearly articulated.** Subject not concerned/ worried about this experience.	**A feeling of perplexity. A stronger sense of uncertainty regarding thoughts than 2.**	**Referential ideas that certain events, objects or people have a particular and unusual significance.** **Feeling that experience may be coming from outside the self. Belief not held with conviction, subject able to question.** Does not result in change in behaviour. May be associated with mild distress.	**Unusual thoughts that contain completely original and highly improbable material.** **Subject can doubt (not held with delusional conviction), or which the subject does not believe all the time.** May result in some change in behaviour, but minor. May be frightening or associated with some distress.	**Unusual thoughts containing original and highly improbable material held with delusional conviction (no doubt).** May have marked impact on behaviour. May be very distressing

Basis of Rating?_____

Onset dates: _____ ***Offset dates*:** _____

Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week **– less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR**	3 to 6 times a week - **more** than an hour per occasion **OR**	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

			3 to 6 times a week - **less** than one hour per occasion	daily – **less** than an hour per occ.		

Do you use Alcohol Y/N Do you use street drugs Y/N - Pattern of Symptoms?

0	**1**	**2**
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)

0 **100**

Not At All Distressed Extremely Distressed

1.2 NON-BIZARRE IDEAS

Non-Bizarre Ideas ('Crystallized Ideas')

- Suspiciousness, Persecutory Ideas (may include ideas of reference if directly related): Has anybody been giving you a hard time or trying to hurt you? Do you feel like people have been talking about you, laughing at you, or watching you? What is it like? How do you know this?

- Ideas of Guilt: Do you feel you deserve punishment for anything you have done wrong?

- Somatic Ideas: Have you had the feeling that something odd is going on with your body that you can't explain? What is it like? Do you feel that your body has changed in some way, or that there is a problem with your body shape?

- Nihilistic Ideas: Have you ever felt that you, or a part of you, did not exist, or was dead? Do you ever feel that the world does not exist?

- Religious Ideas: Are you very religious? Have you had any religious experiences?

- Grandiose Ideas: Have you been feeling that you are especially important in some way, or that you have powers to do things that other people can't do?

- Erotomanic Ideas: Is anyone in love with you? Who? How do you know this? Do you return his/her feelings?

- Jealous Ideas: Are you a jealous person? Do you worry about relationships that your spouse/girlfriend/boyfriend has with other people?

NON-BIZARRE IDEAS - GLOBAL RATING SCALE

0 **Never, absent**	1 **Questionable**	2 **Mild**	3 **Moderate**	4 **Moderately Severe**	5 **Severe**	6 **Psychotic & Severe**
No non-bizarre ideas.	**Subtle changes that could be reality based.** Eg. Very self-conscious.	**Increased self-consciousness** **Or feeling of increased self-importance. Subject able to question.** Eg. Feeling that others look at the subject, or talk about the subject.	**Odd or unusual thoughts but whose content is not entirely implausible- may be some logical evidence.** More evidence than rating of 4. Not necessarily distressing or associated with any change in behaviour. Content of thoughts not original i.e. jealousy, mild paranoia.	**Clearly idiosyncratic beliefs, which although 'possible' have arisen without logical evidence.** Less evidence than rating of 3. Eg. Thoughts that others wish the subject harm, which can be easily dismissed. Thoughts of having special powers, which can be easily dismissed. May be associated with mild distress.	**Unusual thoughts about which there is some doubt (not held with delusional conviction), or which the subject does not believe all the time.** May result in some change in behaviour, but minor. May be frightening or associated with some distress.	**Unusual thoughts containing original and highly improbable material held with delusional conviction (no doubt).** May be associated with marked change in behaviour. May be very distressing

***Basis of Rating?*_____**

***Onset dates:*_____ *Offset dates*: _____**

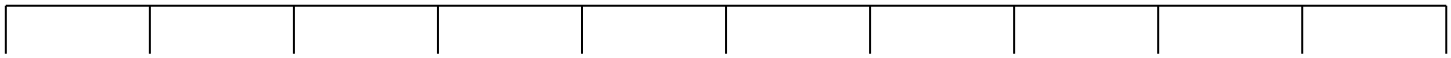
Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week **– less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms?

0	**1**	**2**
No relation to substance use/stress noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

1.3 PERCEPTUAL ABNORMALITIES

Visual Changes

- Distortions, illusions: Is there a change in the way things look to you? Do things somehow look different, or abnormal? Are there alterations in colour, or brightness of objects (things seeming brighter, or duller in colour)? Are there alterations in the size and shape of objects? Do things seem to be moving?
- Hallucinations: Do you have visions, or see things that may not really be there? Do you ever see things that others can't, or don't seem to? What do you see? At the time that you see these things, how real do they seem? Do you realise they are not real at the time, or only later?

Auditory Changes

- Distortions, illusions: Is there any change in the way things sound to you? Do things somehow sound different, or abnormal? Does your hearing seem more acute, or have increased sensitivity? Does your hearing seem muted, or less acute?
- Hallucinations: Do you ever hear things that may not really be there? Do you ever hear things that other people seem not to (such as sounds or voices)? What do you hear? At the time you hear these things, how real do they seem? Do you realise they are not real at the time, or only later?

Olfactory Changes

- *Distortions, illusions: Does your sense of smell seem to be different, such as more, or less intense, than usual?*
- *Hallucinations: Do you ever smell things that other people don't notice? At the time, do these smells seem real? Do you realise they are not real at the time, or only later?*

Gustatory Changes

- *Distortions, illusions: Does your sense of taste seem to be different, such as more, or less intense, than usual?*
- *Hallucinations: Do you ever get any odd tastes in your mouth? At the time that you taste these things, how real do they seem? Do you realise they are not real at the time, or only later?*

Tactile Changes

- *Distortions, illusions, hallucinations: Do you ever get strange feelings on, or just beneath, your skin? At the time that you feel these things, how real do they seem? Do you realise they are not real at the time, or only later?*

Somatic Changes

NOTE: Probes also used to rate Impaired Bodily Sensation, p.26

- *Distortions, illusions: Do you ever get strange feelings in your body (eg feel that parts of your body have changed in some way, or that things are working differently)? Do you feel/think that there is a problem with some part, or all of your body, i.e. that it looks different to others, or is different in some way? How real does this seem?*
- Hallucinations: Have you noticed any change in your bodily sensations, such as increased, or reduced intensity? Or unusual bodily sensations such as pulling feelings, aches, burning, numbness, vibrations?

Positive Symptoms – Perceptual Abnormalities

PERCEPTUAL ABNORMALITIES - GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Severe	6 Psychotic & severe
No abnormal perceptual experience.	**Questionable perceptual changes**	**Heightened, or dulled perceptions, distortions, illusions (eg lights/ shadows).** Not distressing. Hypnogogic/ hypnopompic experiences	**More puzzling experiences: more intense/vivid distortions/ illusions, indistinct murmuring, etc.** **Subject unsure of nature of experiences.** Able to dismiss. Not particularly distressing. Derealisation/ depersonalis[n]	**Much clearer experiences than 3 such as name being called, hearing phone ringing etc, but may be fleeting/ transient.** **Able to give plausible explanation for experience.** May be associated with mild distress.	**True hallucin-ations i.e. hearing voices or conversation, feeling something touching body.** **Subject able to question experience with effort.** May be frightening or associated with some distress. May result in some change in behaviour, but minor.	**True hallucinations which the subject believes are true at the time of, and after, experiencing them.** May be very distressing May have marked impact on behaviour.

Basis of Rating?_____

Onset date: _____ _____ ***Offset date*:** _____

Frequency and Duration

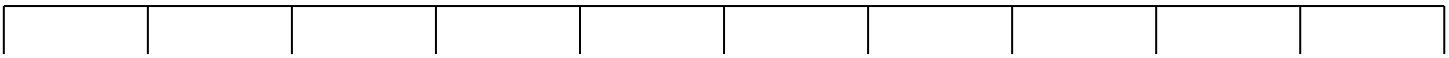
0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week **– less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Positive Symptoms – Perceptual Abnormalities

Pattern of Symptoms?

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

1.4 DISORGANISED SPEECH

Subjective Change:

- Do you notice any difficulties with your speech, or ability to communicate with others?
- Do you have trouble finding the correct word at the appropriate time?
- Do you ever use words that are not quite right, or totally irrelevant?
- Have you found yourself going off on tangents when speaking and never getting to the point? Is this a recent change?
- Are you aware that you are talking about irrelevant things, or going off the track?
- *Do other people ever seem to have difficulty in understanding what you are trying to say/trouble getting your message across?*
- *Do you ever find yourself repeating the words of others?*
- *Do you ever have to use gesture or mime to communicate due to trouble getting your message across? How bad is this?*
- *Does it ever make you want to stay silent and not say anything?*

Objective Rating of Disorganised Speech

- *Is it difficult to follow what the subject is saying at times due to using incorrect words, being circumstantial or tangential?*
- *Is the subject vague, overly abstract or concrete? Can responses be condensed?*
- *Do they go off the subject often and get lost in their words? Do they appear to have difficulty finding the right words?*
- *Do they repeat words that you have used or adopt strange words (or 'non-words') in the course of regular conversation?*

DISORGANISED SPEECH- GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately Severe	5 Severe	6 Psychotic & severe
Normal logical speech, no disorganisation, no problems communicating or being understood.	**Questionable changes in speech**	**Slight subjective difficulties** eg problems getting message across. Not noticeable by others.	**Somewhat vague, some evidence of circumstantiality or irrelevance in speech.** Feeling of not being understood.	**Clear evidence of mild disconnected speech and thought patterns. Links between ideas rather tangential.** Increased feeling of frustration in conversation.	**Marked circumstantiality, or tangentiality in speech, but responds to structuring in interview.** May have to resort to gesture, or mime to communicate.	**Lack of coherence, unintelligible speech, significant difficulty following line of thought.** Loose associations in speech.

***Basis of Rating?*_____**

Onset date: _____ ***Offset date*:**_____ _____

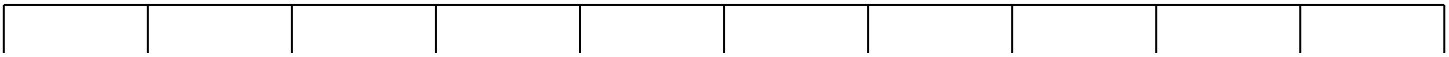
Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week **– less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms?

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

5.4 AGGRESSION/DANGEROUS BEHAVIOUR

- Have you been feeling angry, or irritable recently? Has there been a reason for this? Have you felt more irritated than usual at small things? Have you been in more arguments with others than usual recently? Have you been taking more risks (i.e. when driving) recently than usual? Have others commented that your behaviour is becoming risky, or unsafe? Have you felt like striking out at people or objects recently (more so than usual)?
- Have you become so angry at someone that you have had thoughts of hurting them, or destroying their property? Have you acted on these thoughts?

Questions for Informants:

- Has the subject been acting in an aggressive or dangerous manner recently? Have there been any recent episodes of anger outbursts/physical confrontation? Is this how the subject normally behaves? Have others commented on a change in their level of anger, or irritability? Has the subject destroyed property lately (in association with anger)? Have you felt safe with the subject recently (i.e. when driving, at otherwise normal times)?

AGGRESSION/DANGEROUS BEHAVIOUR- SEVERITY RATING SCALE

0	1	2	3	4	5	6
No aggressive, or dangerous behaviour reported by the subject or others.	Questionable	Slight irritability but not associated with rise in aggressive behaviour. May be attributed to events by subject.	More marked increase in irritability/anger towards self/others. May be expressed verbally, or physically in restrained manner (i.e punching pillow etc). May be noted by subject only.	Marked increase in irritability towards others expressed in increased propensity to verbal confrontations with threat of physical aggression. Noted by others and subject.	Aggressive behaviour results in property damage, or harm to others. Subject reports some level of control over anger.	Dangerousness in conjunction with anger at very destructive level, resulting in some considerable physical damage to others, or property. Dominates clinical picture. May attract attention of police etc.

Onset date: _____ ***Offset date*:** _____

Frequency and Duration

0	1	2	3	4	5	6

Absent	Less than once a month	Once a month to twice a week **– less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms?

0	**1**	**2**
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

7.3 SUICIDALITY AND SELF HARM

- Have you had any thoughts recently about harming, or killing yourself? How often have you felt this way?

- Have you had any thoughts of what you would do to achieve this?

- Have you acted on those thoughts at all? What happened?

SUICIDALITY- SEVERITY RATING SCALE

0	1	2	3	4	5	6
Not present.	Questionable	Occasional thoughts of being tired of living. Occasional thought of self-harm. No suicidal thoughts, or plans.	Feeling of being better off dead. Suicidal thoughts, with only vague plan. Able to be distracted from thoughts with some effort. **OR** Minor actions of self-harm (slight scratches etc).	Thoughts of suicide more frequent with associated plan. May be more seriously considering attempt with specific plan. **OR** Impulsive attempts using non-lethal method, or with knowledge of potential for being found.	Clear expression of wanting to kill self. **OR** Potentially serious, or lethal attempt with knowledge of possible rescue.	Specific plan and attempt. **OR** Serious attempt that clearly could have been fatal.

Onset date: _____ ***Offset date*:**_____ _____

Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week – **less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms?

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

SOFAS

[If under 16, please use the C-GAS as per operational policy]

SOFAS: When scoring consider social, and occupational functioning on a continuum from excellent functioning to grossly impaired functioning. Include impairment in functioning due to physical health (or environmental) limitations. To be counted, impairment must be a direct consequence of mental health and/or physical health problems. The effects of lack of opportunity and other environmental limitations are not to be considered.

Code (Note: Use intermediate codes when appropriate, e.g., 45, 68, 72.)

100 Superior functioning in a wide range of activities.

|

91

90 Good functioning in all areas, occupationally and socially effective.

|

81

80 No more than a slight impairment in social, occupational, or school functioning (e.g.

| infrequent interpersonal conflict, temporarily falling behind in schoolwork).

71

70 Some difficulty in social, occupational, or school functioning, but generally functioning well, | has some meaningful interpersonal relationships.

61

60 Moderate difficulty in social, occupational, or school functioning (e.g., few friends, conflicts | with peers or co-workers).

51

50 Serious impairment in social, occupational, or school functioning (e.g., no friends, unable

| to keep a job).

41

40 Major impairment in several areas, such as work or school, family relations (e.g.,

| depressed man avoids friends, neglects family, and is unable to work; child frequently

31 beats up younger children, is defiant at home, and is failing at school).

30 Inability to function in almost all areas (e.g., stays in bed all day; no job, home, or

| friends).

21

20 Occasionally fails to maintain minimal personal hygiene; unable to function independently.

|

11

10 Persistent inability to maintain minimal personal hygiene. Unable to function without

| harming self or others or without considerable external support (e.g., nursing care and

1 supervision).

0 Inadequate information.

NOTES_____
_____
_____
_____
_____
_____
_____
_____
_____

Note: The rating of overall psychological functioning on a scale of 0–100 was operationalized by Luborsky in the Health-Sickness Rating Scale. (Luborsky L: "Clinicians' Judgments of Mental Health." *Archives of General Psychiatry* 7:407–417, 1962). Spitzer and colleagues developed a revision of the Health-Sickness Rating Scale called the Global Assessment Scale (GAS) (Endicott J, Spitzer RL, Fleiss JL, et al.: "The Global Assessment Scale: A Procedure for Measuring Overall Severity of Psychiatric Disturbance." *Archives of General Psychiatry* 33:766–771, 1976). The SOFAS is derived from the GAS and its development is described in Goldman HH, Skodol AE, Lave TR: "Revising Axis V for DSM-IV: A Review of Measures of Social Functioning." *American Journal of Psychiatry* 149:1148–1156, 1992.

Highest Score in past year OR score at baseline / last assessment			**SCORE A**	
Current Score			**SCORE B**	
Difference between score A & score B			**SCORE C**	
Percentage calculation	**SCORE C**	**x 100 ÷**	**SCORE A**	**= %**

Outcome

Please tick

30% drop in SOFAS score from premorbid level, sustained for a month, occurred within past 12 months	
Chronic Low Function CRITERIA = SOFAS score of 50 or below maintained for 12 months or longer	

8: INCLUSION CRITERIA

INTAKE CRITERIA CHECKLIST

Group 1: ARMS Vulnerability Group

This criterion identifies young people at risk of psychosis due to the combination of a trait risk factor and a significant deterioration in mental state and/or functioning

	YES	NO
• **Family history of psychosis** in first degree relative **OR Schizotypal Personality Disorder** in identified patient	☐	☐
PLUS		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 1 – Vulnerability Group	☐	☐

Group 2: ARMS Attenuated Psychosis Group (2a OR 2b)

This criterion identifies young people at risk of psychosis due to a subthreshold psychotic syndrome. That is, they have symptoms which do not reach threshold levels for psychosis due to subthreshold intensity (the symptoms are not severe enough) or they have psychotic symptoms but at a subthreshold frequency (the symptoms do not occur often enough).

	YES	NO
2a) Subthreshold intensity:		
• **Global Rating Scale Score of 3-5** on *Unusual Thought Content* subscale, **3-5** on *Non-Bizarre Ideas* subscale, **3-4** on *Perceptual Abnormalities* subscale, **or 4-5** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of 3-6** on *Unusual Thought Content, Non-Bizarre Ideas*, *Perceptual Abnormalities* **or** *Disorganised Speech* subscales of the CAARMS…	☐	☐
• …for **at least a week**	☐	☐
2b) Subthreshold frequency:		
• **Global Rating Scale Score of 6** on *Unusual Thought Conten*t, **6** on Non-Bizarre Ideas, **5-6** on *Perceptual Abnormalities* **or 6** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of 3** on *Unusual Thought Content*, *Non-Bizarre Ideas*, *Perceptual Abnormalities* **or** *Disorganised Speech* subscales of the CAARMS	☐	☐

PLUS (for both Group 2 categories)		
• **Symptoms present in past year**	☐	☐
PLUS (for both Group 2 categories)		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 2 – Attenuated Psychosis Group	☐	☐

Group 3: ARMS BLIPS Group

This criterion identifies young people at risk of psychosis due to a recent history of frank psychotic symptoms that resolved spontaneously (without antipsychotic medication) within one week.

	YES	NO
• **Global Rating Scale Score of 6** on *Unusual Thought Content* subscale, **6** on *Non-Bizarre Ideas*, **5 or 6** on *Perceptual Abnormalities* subscale **or 6** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of 4-6** on *Unusual Thought Content*, *Non-Bizarre Ideas*, *Perceptual Abnormalities* **or** *Disorganised Speech* subscales	☐	☐
PLUS		
• **Each episode of symptoms is present for less than one week** and symptoms spontaneously remit on every occasion.	☐	☐
PLUS		
• **Symptoms occurred during last year**	☐	☐
PLUS		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 3 – BLIPS Group	☐	☐

9: PSYCHOSIS THRESHOLD /ANTI-PSYCHOTIC TREATMENT THRESHOLD

	YES	NO
• **Severity Scale Score of 6** on *Unusual Thought Content* subscale, **6** on *Non-Bizarre Ideas*, **5 or 6** on *Perceptual Abnormalities* subscale **and/or 6** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of greater than or equal to 4** on *Unusual Thought Content*, *Non-Bizarre Ideas, Perceptual Abnormalities* **and/or** *Disorganised Speech* subscales	☐	☐
PLUS		
• Symptoms present for **longer than one week**	☐	☐
PSYCHOSIS THRESHOLD CRITERION MET	☐	☐

Greenwood KE, Sweeney A, Williams S, Garety P, Kuipers E, Scott J, Peters E. (2010). CHoice of Outcome In Cbt for psychosEs (CHOICE): The Development of a New Service-User led Outcome Measure of CBT for Psychosis. Schizophrenia Bulletin 36(1) 126-135.

CHOICE (psychosis)

This questionnaire has been developed by asking the opinions of people who have used Cognitive Behaviour Therapy (CBT) to help with their unusual distressing experiences. It looks at the sorts of things that you may want to work on in CBT. It should take 8- 10 minutes to complete.

The questionnaire is made up of 21 statements. You can either fill it in on your own, or we can go through it together.

For each statement, please begin by reading it carefully. You will then be asked to answer the same 2 questions about each statement. Please put a cross on the line for each question to show how you have felt about it over the last week. For each statement the questions will be:

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 not at all satisfied
very satisfied

1. The ability to approach problems in a variety of ways

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

2. Self-confidence

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

3. Positive ways of relating to people

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

4. The effect of unpleasant experiences (e.g. beliefs, thoughts, voices, feelings) on my life

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

5. Feeling overwhelmed by negative feelings (e.g. fear, depression, anger)

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

6. Knowing I am not the only person who has unusual experiences

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

7. The ability to question the way I look at things

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

8. The ability to relax

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

9. Coping:

(i) Ways of dealing with everyday life stresses

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

(ii) Ways of dealing with distressing experiences (e.g. beliefs, thoughts, voices)

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

(iii) Ways of dealing with unpleasant feelings and emotions (e.g. depression, worry, anger)

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

(iv) Ways of dealing with a crisis

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

(v) Ways of dealing with group situations

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

10. Feeling that there is someone who understands and listens to me

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

11. The ability to see things from another point of view

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

12. Feeling safe and secure

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

13. Facing my own upsetting thoughts and feelings

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

14. Peace of Mind

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

15. Feeling happy

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

16. Understanding myself and my past

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

17. Understanding my experiences (e.g. beliefs, thoughts, voices, and related feelings)

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

18. Positive ways of thinking

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied very satisfied

19. A positive purpose and direction in life

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

20. A sense of being in control of my life

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

21. This is a space to write one or two other important goals that you would like to achieve through therapy.

Issue 1 _____

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst
best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied
very satisfied

Issue 2 _____

(a) How would you rate yourself for this?

0 1 2 3 4 5 6 7 8 9 10 worst best

(b) How satisfied are you with this?

0 1 2 3 4 5 6 7 8 9 10 Not at all satisfied

The Questionnaire about the Process of Recovery (the QPR): Guidelines for Clinicians, Researchers and Service Users for the uses, administration and scoring of the QPR

Developed by: Sandra T. Neil, Liz Pitt, Martina Kilbride, Anthony P. Morrison, Sarah Nothard, Mary Welford and William Sellwood in collaboration with The Bolton Salford and Trafford Service User Steering Committee
15 item version developed by: Heather Law, Sandra T. Neil, Graham Dunn and Anthony P. Morrison

What is the QPR? The QPR is a 15 item measure developed from service users' accounts of recovery from psychosis in collaboration with local service users. The idea of the QPR is to ask people about aspects of recovery that are meaningful to them. The QPR is reliable and valid and is strongly associated with general psychological wellbeing, quality of life and empowerment all of which are crucial in recovery from psychosis.

What are the applications of the QPR?

- **Clinical practice**: Because the QPR asks about aspects of recovery that are important to service users this measure could help to facilitate communication and engagement. The QPR may be used to illustrate to people that other individuals progressed to achieve similar goals and this positive message might instil hope, which is crucial to recovery.
    - The QPR could be used both as a tool for setting goals for individual outcomes and as a measure of achievement of these individual goals. For example, the QPR could be used to help people open up, give them structure and offer a focus for individual goals they could work towards and then be used to track progress and provide evidence of this.
    - The sensitivity of QPR is currently being evaluated, to assess the QPR's use as a measure of service effectiveness and as a routine outcome measure.
- **Research**: It is suggested that researchers could use the QPR to expand and add to the evidence base in the area of recovery

How do I administer the QPR? The service users involved in the development of the QPR suggest that before administering the QPR clinicians or researchers using this measure should ensure that:

- All service users who are asked to complete the QPR are given general information (as above) about the measure and are provided with an explanation as to why they are being asked to complete this questionnaire, such as "It is hoped through asking you to complete this measure that we can identify the areas in your life where things are going well and also any areas where you might be having difficulties."
- All service users must give their written or verbal consent to complete the QPR
- The QPR should where possible be completed with another professional or person with whom they can discuss any issues raised.
- The QPR should be used judiciously and responsibly by clinicians, and service users who are in crisis and / or very distressed **should not** be asked to complete the QPR
- The QPR should not be used in a sterile manner, but rather as a vehicle to facilitate discussion about individual goals.

How do I score the QPR? The QPR has 15 items each scored on a 4-point scale (0= disagree strongly, 1=disagree, 2=neither agree nor disagree, 3=agree, 4=agree strongly). Higher scores are indicative of recovery. However, those involved in developing this measure suggest that total scores should not only be added to give total recovery scores, but the QPR should be used as described above e.g. as a tool for engagement, setting goals relative to the individual and as a measure of outcome for these.

PLEASE TURN OVER THE PAGE AND CONTINUE OVERLEAF

The Questionnaire about the Process of Recovery (QPR)

[15/10/2007- Version 1]
[02.04.2014 Version 2]

We developed this questionnaire in order to understand more about the process of recovery; what's helpful and what's not so helpful. Everyone is different and there will be differences for everyone. The items on this questionnaire were developed through a process of interviewing service users about their recovery journeys. We hope that by filing in this questionnaire you will help us find out information that is important to you and your own recovery. Not all factors will be important to you, since everyone is different. This questionnaire is not intended to be used to impose anything against your wishes.

If you would like to fill in the questionnaire, please take a moment to consider and sum up how things stand for you at the present time, in particular over the last 7 days, with regards to your mental health and recovery. Please respond to the following statements by putting a tick in the box which best describes your experience.

		Disagree strongly	Disagree	Neither agree nor disagree	Agree	Agree Strongly
1.	I feel better about myself					
2.	I feel able to take chances in life					
3.	I am able to develop positive relationships with other people					
4.	I feel part of society rather than isolated					
5.	I am able to assert myself					
6.	I feel that my life has a purpose					
7.	My experiences have changed me for the better					
8.	I have been able to come to terms with things that have happened to me in the past and move on with my life					
9.	I am basically strongly motivated to get better					
10.	I can recognise the positive things I have done					
11.	I am able to understand myself better					
12.	I can take charge of my life					
13.	I can actively engage with life					
14.	I can take control of aspects of my life					
15.	I can find the time to do the things I enjoy					

Thank you for completing this questionnaire

ABOUT YOUR OVERALL QUALITY OF LIFE

Please indicate which statements best describe your overall quality of life at the moment by placing a tick (✓) in **ONE** box for each of the five groups below.

1. Feeling settled and secure

I am able to feel settled and secure in **all** areas of my life	4
I am able to feel settled and secure in **many** areas of my life	3
I am able to feel settled and secure in **a few** areas of my life	2
I am **unable** to feel settled and secure in **any** areas of my life	1

2. Love, friendship and support

I can have **a lot** of love, friendship and support	4
I can have **quite a lot** of love, friendship and support	3
I can have **a little** love, friendship and support	2
I **cannot** have **any** love, friendship and support	1

3. Being independent

I am able to be **completely** independent	4
I am able to be independent in **many** things	3
I am able to be independent in **a few** things	2
I am **unable** to be at all independent	1

4. Achievement and progress

I can achieve and progress in **all** aspects of my life	4
I can achieve and progress in **many** aspects of my life	3
I can achieve and progress in **a few** aspects of my life	2
I **cannot** achieve and progress in **any** aspects of my life	1

5. Enjoyment and pleasure

I can have **a lot** of enjoyment and pleasure	4
I can have **quite a lot** of enjoyment and pleasure	3
I can have **a little** enjoyment and pleasure	2
I **cannot** have **any** enjoyment and pleasure	1

Please ensure you have only ticked **ONE** box for each of the five groups.

ICECAP-A measure V2

Revised Satisfaction with Therapy and Therapist Scale (Oei & Shuttlewood, 1999; Oei & Green, 2008)

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I am satisfied with the therapy	1	2	3	4	5
The therapist listened to what I had to say	1	2	3	4	5
The therapy helped me with the things I needed help with	1	2	3	4	5
The therapist provided a good explanation of the treatment	1	2	3	4	5
I would recommend the therapy to someone with a similar problem	1	2	3	4	5
The therapist was critical towards me	1	2	3	4	5
The therapist seemed to know what they were talking about	1	2	3	4	5
The therapist was friendly	1	2	3	4	5
I believe the therapy will help me with my problem	1	2	3	4	5
The therapy focused on problems that I was concerned about	1	2	3	4	5
The therapist seemed to understand what I was thinking and feeling	1	2	3	4	5

Appendix B – Contents

PARTICIPANT INFORMATION SHEET FOR MUSE-ARMS

Participant Information Sheet

Study Title: Managing Unusual Sensory Experiences in At Risk Mental States for psychosis

Researchers: Dr Guy Dodgson, Dr Ben Alderson-Day, Professor Charles Fernyhough, Dr Steph Common and Dr Rob Dudley

We would like to invite you to take part in a new research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read this information sheet and discuss it with others, if you wish. One of our team will contact you in a few days and go through the information sheet with you and answer any questions you have. Ask us if there is anything that is not clear, or if you need more information. This is your copy of this information sheet, for you to keep for future reference.

What is the purpose of the study?
We are interested in seeing how well a new therapy for unusual sensory experiences works. We have developed a treatment that tries to help people understand and manage these experiences. We have used this treatment with some people and they have found it acceptable. The novel treatment is delivered with help of a tablet-computer and is used to identify different types of unusual experiences that people might have. Once the type of experience has been identified the therapist tries to understand with you how this experience developed and looks at different ways that you might try to manage the experience that would reduce any distress you experience or impact on your lifestyle. Your therapist would work through a series of topics on a tablet that they think will help you. These topics cover a range of things, such as how the mind works, the types of experiences other people have and ways of coping that other people have found helpful.

We now want to see if the treatment is acceptable to people with less extreme forms of unusual sensory experiences, who may not have had the experiences for as long.

Why have I been invited?
You are being invited to take part because you are starting therapy for unusual sensory experiences, because you have a good understanding of English, because you have these experiences at least once per week, and because you are aged 16 years or over.

Do I have to take part?
It is up to you to decide whether or not to take part. However, you might find it helpful to talk to others (e.g., a family member or a friend) about this. If you decide to take part, you will still be free to withdraw at any time, and you will not have to give a reason for withdrawing. If you decide not to take part, or if you withdraw from the study at a later date, the care you receive will not be affected in any way.

What will happen to me if I take part?
If you agree to take part, a researcher will arrange to meet you at a mutually convenient time and location for two assessments. We think the assessments will between 1.25-2 hours. They will involve you answering questions about your unusual sensory experiences (e.g., about how often you have them, what you think is happening), about your mood, about your quality of life (e.g., how satisfied you are with your financial situation, your work, and your relationships), and about your feelings about the therapy you received. In total, you will complete about 3 to 3.5 hours of assessments, spread over two sessions, if you decide to take part.

The first assessment will take place as soon as possible, ideally before your next appointment with your therapist. The second assessment will take place after you have completed the treatment, which we think will takes about 2-4 appointments with your therapist. During the second assessment we will ask whether we can audio record your answers to questions about how you have found the therapy and any suggestions you have about it. The recording devise is encrypted, to ensure that what you say is confidential and secure. Your views on the therapy are not shared with the therapist, but are to only to help us to understand how helpful the treatment is and how we can improve it.

In total, therefore, you would be involved with the study for about 6 weeks. Your work with the therapist might take longer than 6 weeks and address other problems too. You will only be involved in the research when working on unusual experiences is the focus of your therapy. After you have completed 2-4 sessions of therapy, we will ask your therapist to answer some questions, which parts of the treatment they used, whether they thought it helped them offer you better care and how we could improve the treatment.

How will my care be affected by taking part?
In broad terms, the care you receive will not be affected by whether or not you decide to take part in this study. Your therapist will have access to the treatment whether you agree to participate or not. They will decide with you what the most appropriate treatment is and offer you it, whether you participate or not. One difference is that the therapists will be able to receive supervision on the care offered to participants in the study, from the researchers.

Expenses and payments
To thank you for taking part in this research and to compensate you for the time you will spend taking part in the study, you will be given a £20 gift voucher at each assessment. If you have to travel to meet with a researcher, your travel expenses will be reimbursed.

Are there any risks in taking part?
The only potential risk is that you may find it distressing to answer the researchers' questions during your appointments with them. It is absolutely fine to take a break or stop the session if this occurs.

What are the possible benefits of taking part?
The main benefit for you is the knowledge that you are taking part in research that is likely to help improve the care that is provided to people with mental health problems.

Will my taking part in the study be kept confidential?
We will send a letter to your GP explaining that you are taking part in the study, but other than that your participation will remain confidential. All of the information you provide in the study will be confidential. However, if you disclose information which indicates that you intend to harm yourself or others, confidentiality will have to be broken and we will have to inform the relevant authority (e.g., your doctor).

Northumberland, Tyne, & Wear (NTW) NHS Foundation Trust is the sponsor for this study based in the United Kingdom, in collaboration with Durham University. We will be using information from you and your medical records in order to undertake this study and Durham University will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Durham University will keep identifiable information about you for five years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/.

Researchers from Tees, Esk, and Wear Valley (TEWV) NHS Foundation Trust will collect information from you and your medical records for this research study in accordance with our instructions. TEWV will keep your name and contact details confidential and will not pass this information to NTW. TEWV will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from NTW, Durham University, and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NTW will only receive information without any identifying information. The people who analyse the information at NTW will not be able to identify you and will not be able to find out your name or contact details.

All the data we collect will be stored on a password protected computer accessible only to the research team. Hard copies of consent forms and questionnaires that you provide will be kept in a locked cabinet at Durham University. Any audio recordings we make will be stored on an encrypted voice recorder before being transferred to a secure server at Durham University. Transcriptions of those recordings will be made by a professional transcriber, with whom Durham University have a confidentiality agreement. Any study data you provide will be stored under an anonymous code and

separately from personal data, to minimise the chance of anybody being able to identify you from your data. Audio recordings will be stored separately from all other data. TEWV and Durham University will keep identifiable information about you from this study for 5 years after the study has finished.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. If you chose to do so, we will ask you if you are happy for us to use the information gathered up to the period of your withdrawal. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decision to withdraw is linked to the treatment being offered, we would ask that we can use this information, as this is important information about whether the treatment is acceptable to participants.

If you become very unwell during the study, you will be withdrawn from the study (i.e. you would stop taking part), but we would keep the information you had provided up to that point.

What if there is a problem?
If you are unhappy, or if there is a problem, please let us know by contacting Dr Guy Dodgson on 01670 844670 (guy.dodgson@ntw.nhs.uk) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with, then you should contact Keeley Brickle, Acting Complaints and Patient Advice and Liaison Service Manager, on 0191 245 6679 or via complaints@ntw.nhs.uk. When contacting the Complaints Service, please provide details of the name or description of the study (so that it can be identified), the researcher involved, and the details of the complaint you wish to make. The insurance cover for the management and conduct of this study is provided by the sponsor, NTW, under the NHS indemnity scheme. The insurance cover for the design of the research is provided by NTW and Durham University's public liability and professional indemnity insurance.

What will happen to the results of the study?
The results of the study will be submitted for publication with scientific journals. All the participants will be informed of the study results and how to access these publications by letter. No publication that uses data from this study will include your personal details or information that can identify you in any way.

Further information and contact details
If you have any further questions or things that you would like to see clarified before you decide if you want to take part or not, please free to contact our research team.

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Early Intervention in Psychosis (Redcar)
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07789032473
Stephanie.common@nhs.net

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Dr Ben Alderson-Day
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Professor Charles Fernyhough
Caedmon Building
Durham University
Leazes Road
Durham
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0191 3348143
c.p.fernyhough@durham.ac.uk

CONSENT FORM FOR PARTICIPANTS IN MUSE-ARMs

Consent Form

Title of study: Managing Unusual Sensory Experiences in people with an At Risk Mental State for Psychosis

Researchers: Dr Guy Dodgson, Dr Ben Alderson-Day, Professor Charles Fernyhough, Dr Steph Common, Dr Rob Dudley

Participant identification number for this study: ……

	Please sign each box with your initials
I confirm that I have read and have understood the information sheet (dated 12.10.18 ; version 2) for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily by the researcher.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my care or my rights being affected.	☐
I understand that, under the Data Protection Act, I can at any time ask for access to the information I have provided and that I can also request the destruction of that information if I wish.	☐
I agree to my General Practitioner being informed of my participation in the study.	☐
I understand that data collected during the study may be looked at by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this study. I give permission for these individuals to have access to this data.	☐

I agree to my therapist answering questions about my treatment and unusual sensory experiences when I have completed my sessions of therapy.	☐
I agree that the research team can have access to the formulation of my unusual sensory experiences that I build with my therapist.	☐
I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers	☐
I consent to the use of audio recording during assessment sessions and understand how these recordings will be stored. I consent to the use of quotes from these recordings being used and understand that they will be made anonymous, for example changing any information that could identify me.	☐
I agree to take part in the above study.	☐

Participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature
_____	_____	_____
Researcher	Date	Signature

The contact details of lead researcher (Principal Investigator) are:
Dr Guy Dodgson, Greenacres Centre, Northumberland, Tyne and Wear NHS Foundation Trust, Green Lane, Ashington, NE63 8BL
Telephone: 01670 844670 Email: guy.dodgson@ntw.nhs.uk

Three copies are collected for each consent process: one copy for participant's GP, one copy for participant medical records, and one copy for the participant.

LETTER TO GP FOR PARTICIPANTS IN MUSE-ARMS

< insert Dr's name here >
Address Line 1
Address Line 2
Address Line 3
Postcode
< insert date here >

Dear Dr < insert name here >

RE: Managing Unusual Sensory Experiences for people with An At Risk Mental State for psychosis

< patient's name and date-of-birth here >

I am writing to inform you that your patient has agreed to participate in the above study. In this open, non-randomised study, your patient will receive standard psychological therapy for voice-hearing, but this therapy will be tailored to the type(s) of hallucinations they report. We will assess their symptoms, quality of life, and perceptions of the therapy they received over the next 6 weeks.

The purpose of this study is to investigate the acceptability of a novel treatment manual for hallucinations, which is already being used by clinicians in some parts of the region. To do this, we are assessing change in symptoms and quality of life reported by participants.

The above patient will receive a therapy that we hope will be more effective than treatment-as-usual. However, the therapy they receive will differ from treatment-as-usual in ways that will have **no implications for any other care they receive.**

I have enclosed a copy of the Participant Information Sheet for your reference. However, if you have any queries or require further information, **please contact me at guy.dodgson@ntw.nhs.uk or on 01670 844670**

Yours sincerely

Dr Guy Dodgson
Consultant Clinical Psychologist
Reginal Clinical Lead for EIP NE and Cumbria

STAFF PARTICIPANT INFORMATION SHEET FOR MUSE-ARMs

Staff Participant Information Sheet

Study Title: Managing Unusual Sensory Experiences in At Risk Mental States for psychosis

Researchers: Dr Guy Dodgson, Dr Ben Alderson-Day, Professor Charles Fernyhough, Dr Steph Common and Dr Rob Dudley

We would like to invite you to take part in a new research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read this information sheet and discuss it with others, if you wish. Ask us if there is anything that is not clear, or if you need more information. This is your copy of this information sheet, for you to keep for future reference.

What is the purpose of the study?
The main objective of this study is to investigate the acceptability of a new treatment manual for Managing Unusual Sensory Experiences (MUSE) in patients with At Risk Mental States (ARMS) for psychosis. Delivered with the help of tablet-computer, the MUSE toolkit helps to identify the type of hallucinations reported by service-users and tailors the treatment according to that. The toolkit uses current theories and models of hallucinations to explain different types of unusual sensory experiences. We are interested in how acceptable this treatment is in the ARMS group, and what it is like for staff to use.

Why have I been invited?
You are being invited to take part because you are a psychological therapist who regularly works with people with ARMS.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part, you will still be free to withdraw at any time, and you will not have to give a reason for withdrawing.

What will happen to me if I take part?
You will be asked to complete treatment adherence measures after each appointment with a service-user, this will involve recording the topics of the manual that you used in treatment. You will be also invited to participate in a short semi structured interview, where we will ask you a few questions about your views and experience of using the MUSE toolkit. With your consent, we will record that interview with an audio recorder.

What are the possible benefits of taking part?
The main benefit for you is the knowledge that you are taking part in research that is likely to help improve the care that is provided to people with mental health problems.

Will my taking part in the study be kept confidential?
Northumberland, Tyne, & Wear (NTW) NHS Foundation Trust is the sponsor for this study based in the United Kingdom, in collaboration with Durham University. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Durham University will keep identifiable information about you for five years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

All the data we collect will be stored on a password protected computer accessible only to the research team. Hard copies of consent forms and questionnaires that you provide will be kept in a locked cabinet at Durham University. Any audio recordings we make will be stored on an encrypted voice recorder before being transferred to a secure server at Durham University. Transcriptions of those recordings will be made by a professional transcriber, with whom Durham University have a confidentiality agreement. Any study data you provide will be stored under an anonymous code and separately from personal data, to minimise the chance of anybody being able to identify you from your data. Audio recordings will be stored separately from all other data. TEWV and Durham University will keep identifiable information about you from this study for 5 years after the study has finished.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. If you chose to do so, we will ask you if you are happy for us to use the information gathered up to the period of your withdrawal. If not, we will destroy the data and no further use will be made of it.

What if there is a problem?
If you are unhappy, or if there is a problem, please let us know by contacting Dr Guy Dodgson on 01670 844670 (guy.dodgson@ntw.nhs.uk) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with, then you should contact Keeley Brickle, Acting Complaints and Patient Advice and Liason Service Manager, on 0191 245 6679 or via complaints@ntw.nhs.uk. When contacting the Complaints Service, please provide details of the name or description of the study (so that it can be identified), the researcher involved, and the details of the complaint you wish to make. The insurance cover for the management and conduct of this study is provided by the sponsor, NTW, under the NHS indemnity scheme. The insurance cover for the design of the research is provided by NTW and Durham University's public liability and professional indemnity insurance.

What will happen to the results of the study?
The results of the study will be submitted for publication with scientific journals. All the participants will be informed of the study results and how to access these publications by letter. No publication that uses data from this study will include your personal details or information that can identify you in any way.

Further information and contact details
If you have any further questions or things that you would like to see clarified before you decide if you want to take part or not, please free to contact our research team.

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CONSENT FORM FOR STAFF PARTICIPANTS IN MUSE-ARMs

Consent Form

Title of study: Managing Unusual Sensory Experiences in people with an At Risk Mental State for Psychosis

Researchers: Dr Guy Dodgson, Dr Ben Alderson-Day, Professor Charles Fernyhough, Dr Steph Common, Dr Rob Dudley

Identification number for this study: ……

	Please sign each box with your initials.
I confirm that I have read and have understood the information sheet dated ……12.10.18…… version ……2…… for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily by the researcher.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	☐
I understand that, under the Data Protection Act, I can at any time ask for access to the information I have provided and that I can also request the destruction of that information if I wish.	☐
I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers	☐
I understand that data collected during the study may be looked at by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this service evaluation. I give permission for these individuals to have access to this data.	☐

I consent to the use of audio recording during assessment sessions and understand how these recordings will be stored.	☐
I agree to take part in the above study.	☐

Participant	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature
_____	_____	_____
Researcher	Date	Signature

The contact details of lead researcher (Principal Investigator) are:
Dr Guy Dodgson, Greenacres Centre, Northumberland, Tyne and Wear NHS Foundation Trust, Green Lane, Ashington, NE63 8BL
Telephone: 01670 844670 Email: guy.dodgson@ntw.nhs.uk

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