Doctoral Thesis

Submitted in partial fulfilment of the Lancaster University Doctorate in Clinical Psychology

Telehealth Imagery Focused Therapy for People with Delusions

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Word Count

Section	Main Text	Appendices, including References, Figures and Tables	Total
Abstract	299	-	299
Literature Review	6,680	8,646	15,326
Empirical Paper	8,658	4,603	13,261
Critical Appraisal	3,927	4,786	8,713
Ethics Section	5,943	4,501	10,444
Total	25,507	22,526	48,043

Thesis Abstract

This thesis explores telehealth imagery focused therapy for people with delusions. Delusions, particularly persecutory delusions, can cause distress and are linked to deterioration in psychological wellbeing. Mental imagery is a factor associated with such distress and interventions targeting this could be beneficial.

Section one reports on a quantitative systematic literature review that examines the outcomes imagery focused interventions for people with psychosis and delusions. Six databases were searched (PsycINFO, PubMed, MEDLINE, Web of Science, EMBASE, CINAHL) and eight studies were found to meet the requirements for inclusion. These studies largely supported their aims in reducing levels of distress and intrusiveness of imagery. Results suggest that interventions targeting mental imagery are acceptable, feasible and safe within a population of people with psychosis. Further research that uses more robust methodological designs and larger sample sizes is needed.

Section two reports on an empirical study that aimed to examine the feasibility and acceptability of a telehealth imagery-based therapeutic intervention for people experiencing persecutory delusions. A non-concurrent A-B multiple-baseline design was used. Five participants, all female, completed multiple baselines (minimum three, maximum five sessions) and six therapy sessions. There was a 100% completion rate of sessions and measures. Participants reported clinically significant improvement on at least one measure and all participants reported a reduction in delusions and the realness and compelling nature of distressing imagery. No adverse effects were found and participant feedback was positive. Limitations of the study include an all-female sample, small sample size and lack of control group. Overall, the delivery of an imagery-focused intervention via telehealth appears to be feasible and acceptable.

Section three includes the critical appraisal which reflects on the process of conducting this project. It summarises prior sections, discusses key considerations of the research and considers future research.

Declaration

This thesis documents research undertaken for the Doctorate in Clinical Psychology at the Division for Health Research, Lancaster University. The work presented here is the author's own, except where due reference is made. The work has not been submitted for the award of a higher of a higher degree elsewhere.

Name: Aimee Joan Cairns

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Date: 11th April 2022

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Firstly I would like to take this opportunity to acknowledge the five participants who took part in the case series. Thank you for your time, and your willingness to 'give it a go'. More importantly, thank you for the courage you demonstrated by sharing your personal experiences. I have learnt so much from our interactions and working with you all was the highlight of compiling thesis. Thank you also to everyone who helped with recruitment and made this research possible.

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Contents

Section One: Systematic Literature Review

The Outcomes of Imagery Focused interventions in Relation to Distress in People with Paranoia:

A Systematic Literature Review[+]

Word count (excluding references, tables and appendices): 6,025

Abstract: 223 words

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†See Appendix A for submission guidelines

Abstract

Purpose

This review aimed to examine the outcomes of imagery focused interventions in people with delusions.

Methods

PsycINFO, PubMed, MEDLINE, Web of Science, EMBASE and CINAHL were systematically searched for studies that included a clinical population with psychosis and delusions and mental imagery. The review was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and quality appraisal of all included papers was completed using the Crowe Critical Appraisal Tool. Information from included texts was extracted and collated on Excel which informed the narrative synthesis of results.

Results

Of 2,736 studies identified, eight were eligible for inclusion and rated for quality with an average score of 70.63%. These studies largely supported their aims in reducing levels of distress and intrusiveness of imagery. Four of the eight studies used case series designs, two were randomised controlled trials and two reported single case studies. It appears that interventions targeting mental imagery were acceptable and well tolerated within a population of people experiencing psychosis and delusions.

Conclusions

Some therapeutic improvement was reported, although the studies consisted of mainly small sample sizes. Whilst some clinical implications are suggested, future research is needed to tackle existing weaknesses of design and explore the outcomes of imagery interventions within this population in larger samples, under more rigorous methodologies.

Keywords: psychosis, mental imagery, imagery, schizophrenia, delusions

Introduction

Background

People with psychosis are known to experience a broad range of symptoms such as hallucinatory experiences, delusional beliefs, thought disorder, paranoia and anhedonia (World Health Organisation, 2019). Bentall's (2006) complaint-orientated approach suggests that separate mechanisms underly each of these symptoms and promotes the development of specific psychological treatments to address the cognitive processes underlying these experiences. Similarly, Freeman (2016), suggests considering these symptoms on a more individual level, as psychotic experiences each require explanation, research, and tailored interventions. Diagnostic categories continue to be widely used; however, research suggests they interfere/obstruct the advancement of our understanding and treatment of psychotic experiences (Freeman & Garety, 2014; Ronald et al., 2013). As such the study of individual experiences of psychosis has gained ground. Peralta and Cuesta (1999) completed a factor analysis of over 600 inpatient psychiatric assessments. They identified 11 first-order factors which corresponded to different symptoms of psychosis. Therefore, research focussed on individual experiences of psychosis corresponds to clinical need and aim to alleviate the experiences that people find most distressing (Freeman, 2016). Paranoia is one of these experiences, a prevalent experience, at a clinical level and in the general population (Freeman et al., 2011). It is thought to exist on a spectrum and encompasses anything from general suspiciousness to persecutory delusions (Freeman et al., 2005). An updated review suggests future treatments for psychosis, and delusions more specifically, focus on understanding and treating individual experiences with an overall aim of reducing the distress and impact of each (Garety & Freeman, 2013). A potential area of focus could be the experience of mental imagery. Within psychosis, experienced clinicians and researchers report that mental imagery

content is often associated with voice content (Turkington et al., 2016) and delusions, e.g. images of being attacked (Morrison et al., 2002).

Mental imagery is generally understood as “seeing with the mind’s eye”, and can involve all five senses, however visual mental imagery is the most commonly experienced and researched (Kosslyn et al., 2001, p. 635). It does not typically require external sensory input (Pearson et al., 2015) and can be triggered by internal and situational stimuli (Çili & Stopa, 2015). Mental images can be mental representations of places, objects or events (Stopa, 2009), may be experienced when craving food (Kemps & Tiggemann, 2015) or imagining potential future events (Berntsen & Jacobsen, 2008). Mental images can be experienced as life-like and result in physiological responses such as increased heart-rate (Cuthbert et al., 2003).

Two highly cited studies found that the majority of participants with psychosis, experienced intrusive images (Morrison et al., 2002; Schulze et al., 2013). Morrison et al., (2002), interviewed 35 people with psychosis spectrum diagnoses about their experience of mental images that accompanied any psychotic symptoms, 74.3% (*n*=26) reported experiencing an image connected to their symptoms. Of these 26, 25 participants linked the image to a particular emotion or belief and 17 associated the image with a memory of a past event. Participants who experienced persecutory delusions reported images related to these feared events, e.g., being attacked with axes, as well as memories of traumatic life events. These results were largely replicated a decade later by Schulze et al., (2013) in a sample of people experiencing persecutory delusions. Of the 40 participants recruited, 72.5% reported intrusive images when they thought, or felt anxious, about their persecutory beliefs. Of this 72.5%, 82.8% rated these images as negative, and 71.4% rated images as distressing. Research has shown that the distressing nature of this imagery could negatively affect psychological wellbeing within people with psychosis (Freeman et al., 2014). Both studies

are limited by small sample sizes, lack of comparison group and lack of assessment of co-morbid experiences such as trauma or anxiety, nonetheless, both studies reported important foundations for this research area.

Imagery-focused interventions

Mental imagery interventions have been a longstanding feature of Cognitive Behavioural Therapy (CBT; Beck, 1976) and in psychotherapy more generally (Edwards, 2007; Singer, 2006). Research suggests that mental imagery is an important feature across all cognitive processes (Kosslyn et al., 1995; Pearson et al., 2015). It has been theorised to have a powerful impact on emotion (Holmes et al., 2008; 2009; Holmes & Mathews, 2010), with empirical evidence indicating that it can elicit stronger emotional responses compared to similar information represented verbally (Pearson et al., 2015). Mathews and MacLeod (2002), suggested that emotions e.g. anxiety and fear are likely to be induced by imagery as the system which generates emotional states evolved prior to language, therefore, is more responsive to sensory-perceptual representations such as imagery. Therefore, our rationale for using imagery-focused intervention is to build on these hypotheses that imagery-focused interventions can reduce the impact of distressing imagery on emotion.

The manipulation of mental images happens frequently, for example, within everyday problem solving such as mental rotation (Shepard & Metzler, 1971) and creative thinking (Pearson et al., 2013). However, before developments in our understanding of imagery and its link to behaviour and emotion, professional training on imagery techniques and interventions was largely absent for clinicians (Saulsman et al., 2019). A range of imagery techniques can be applied therapeutically; enhancing emotional engagement in thought record work (McEvoy et al., 2018), behavioural experiments, (McEvoy et al., 2015), using positive imagery regarding future behaviour to influence actual behaviour (Renner et al., 2017), and imaginal exposure (Foa et al., 1980). Imagery-focused techniques have been supported by a

limited, but growing, body of research (Holmes, Blackwell, et al., 2016; Pile et al., 2021). Interest in another technique, imagery rescripting (Edwards, 2007; van der Hart et al., 1989), has grown rapidly, with it being integrated into treatment across diagnoses and investigated as a stand-alone intervention (Arntz, 2012). Imagery rescripting is frequently introduced as a technique to modify the meaning and emotion attached to a distressing memory; however, it is not restricted to memories. It involves the therapist asking the individual to imagine a traumatic memory or aversive event. The therapist then helps the person rewrite it using a safer narrative (Ehlers & Clark, 2000; Ehlers et al., 2005). An example of integration was researched by Kindt et al., (2008) in a sample of 71 participants with chronic PTSD. Imagery rescripting in conjunction with imaginal exposure led to significantly greater reductions in anger, shame and guilt as compared to scores for the imaginal exposure alone condition and the waiting list condition. A single session of imagery rescripting reportedly reduced distress associated with memories for a small sample (n=14) of people with social phobia, and these improvements were maintained at one week follow-up (Wild & Clark, 2011). Multiple systematic reviews report the effectiveness of imagery rescripting in reducing distressing intrusive cognitions such as voices, thoughts and images, across disorders (Morina et al., 2017; Saulsman et al., 2019).

However, clinicians report a hesitancy to incorporate imagery-focused techniques into their interventions, barriers include; lack of training and concerns that imagery techniques may be destabilising for clients (Bell et al., 2015) Whilst the aforementioned research findings are limited by the focus on newly qualified staff, a similar concern is reported by more experienced colleagues. In a single case study, Newman-Taylor (2020), aimed to overcome the concerns of a staff team and client regarding the use of imagery rescripting for psychotic symptoms by creating a sense of ‘felt security’. Felt security embodies an attachment relationship, a sense of interpersonal safety that is associated with secure,

protective relationships (Sasaki & Overall, 2020). Whilst the felt security imagery task may not be necessary for all clients, it demonstrated a simple way of regulating emotion, increasing acceptability of imagery rescripting and decreasing the hesitancy that surrounds offering imagery focused techniques to people with symptoms of psychosis.

Within a non-clinical sample of students with high levels of trait paranoia, a single session of imagery rescripting reduced paranoia scores and distress, with most participants also reporting 'positive' emotions of 'relief and calmness'. Despite the lack of control group and largely female sample, results suggest that imagery techniques, specifically rescripting, may be beneficial to people with clinical levels of paranoia (Newman-Taylor et al., 2020).

Building upon the success of studies in non-clinical samples, Clarke et al., (2021) explored the feasibility, safety and acceptability of a brief imagery rescripting for self-referential distressing appraisals (e.g. I am vulnerable) associated with trauma memories in people with psychosis. The protocol was built on several imagery rescripting protocols and targeted trauma memories. Participants experienced reliable change on measures of PTSD and wellbeing, with 58.3% of participants meeting criteria for clinically significant improvements of PTSD symptoms. Despite these promising results, delusions were only measured at baseline, and therefore without a post-intervention score for comparison it is not possible to comment on the effectiveness of this imagery focused intervention on delusions.

With more papers in the area of psychosis and imagery being published, alongside an increased clinical interest in the area, a review to establish the evidence base would be helpful and timely. A review to collate studies that focus on imagery interventions for people with psychosis and delusions provides the opportunity to understand what research has been carried out to date and to what extent these interventions have been helpful.

Aims

The main aim of the review was to examine the outcomes of imagery-focused interventions in people delusions. Delusions are the only experience of psychosis explored. A secondary outcome regarding acceptance and feasibility of imagery-focused interventions within this population will also be considered.

Method

This review was informed by the PRISMA statement (Page et al., 2021, Appendix B). The protocol was registered on the international database of prospectively registered systemic reviews, PROSPERO, (registration number: CRD42022322584) and can be accessed at https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022322584.

Search Strategy

An electronic search for eligible articles was conducted on 24/03/2022 in the following databases: PsycINFO, PubMed, MEDLINE, Web of Science, EMBASE and CINAHL. The search strategy was developed by the review team and consisted of two search strings. The first search included, “psychosis OR schizophrenia OR delusion OR psychotic disorder”, the second included “imagery OR mental imagery”. Searches were predominantly keyword searches with truncation around terms associated with mental imagery and psychosis and connected by Boolean Operators (Appendix C). Following full text screening, forward citation and reference list searches were conducted using Google Scholar on included texts.

Inclusion and Exclusion Criteria

As no existing systematic literature review was found, inclusion criteria were kept purposefully broad. This was to increase the potential of all relevant research being included. No restriction was placed on publication date, and papers were included from earliest date to

date of extraction. However, only papers in English language were included, due to lack of resources for translation.

Inclusion criteria consisted of the following: 1) adults of a working age; 2) diagnosis relating to paranoid beliefs; 3) identification of such diagnoses through Diagnostic and Statistical Manual of Mental Disorders (DSM), International Classification of Diseases (ICD), medical records or clinician reports; 4) a measure of delusion pre- and post-intervention; 5) publications focused on mental imagery and imagery techniques; 6) peer reviewed publications with samples from community, inpatient or a mix of both were included, forensic and psychiatric intensive care samples.

Papers were excluded if; 1) participants were under 18 years old; 2) participants had existing neurological disorders; 3) studies focussed on hallucinations; 4) there were no measure of delusions pre- and post-intervention; 5) peer reviewed research focussed on functional magnetic resonance imaging, body image, flashbacks and eye-movement desensitisation and reprocessing (EMDR).

Study Selection

The first author assessed the titles and abstracts of potentially relevant papers. They then reviewed full-text papers against the inclusion and exclusion criteria. Decisions regarding full-text inclusion were discussed and agreed with all authors.

Data Extraction

Relevant demographic, methodological and summary data were extracted and collated using Microsoft Excel (Microsoft Corporation, 2018). To support the aims of the review, key outcomes will be reported, namely changes on measures of delusion and imagery.

Study Quality

All studies were assessed for risk of bias using Crowe Critical Appraisal Tool (CCAT v1.4; Crowe et al., 2011, Appendix D). Assessing for risk of bias allows evidence to be

distinguished from assumptions and misreporting. It also enables results to be interpreted based on the overall quality of the methodology and context in which they were found. Based on empirical evidence, the CCAT was developed to be used across multiple research designs. It consists of 22-items across eight categories and is reported as having a good degree of construct validity (Crowe & Sheppard, 2011). Items for scoring include rationale for intervention/treatment/exposure, potential sources of bias/confounding variables, sampling method and its suitability, and ethical matters. Categories are scored independently using a six-point scale, from zero to five, with higher scores representing high quality within that individual category. Items that are not applicable to the design of the study are excluded. Summary scores are provided; however, these can be misleading and hide very poor scores in one or more categories, therefore, scores across all categories are reported for all included papers.

Results

Study Selection

In line with PRISMA guidelines, Figure 1, outlines the selection process of this review. A total of 2,736 studies were identified through database searches, 1,070 duplicates were removed, and 1,666 papers were screened at title and abstract level. 28 papers were included for full text review and eight papers met all inclusion criteria. No further studies were identified from forward citation and reference list searching and screening.

[FIGURE 1 HERE]

Study Characteristics and Participants

The eight studies were published between 2004 and 2022 and assessed a total of 102 participants. Table 1 summarises study characteristics. Two studies reported single case

studies (Morrison, 2004; Serruya & Grant, 2009) Two studies were randomised controlled trials (RCT; Ascone et al., 2017; Sheaves et al., 2019) and the remaining four studies used case series designs (Forkert et al., 2021; Pitfield et al., 2020; Sheaves et al., 2015; Taylor et al., 2020). Six studies were conducted within the United Kingdom, one in Germany (Ascone et al., 2017) and one in the United States of America (Serruya & Grant, 2009). Four studies included follow-ups within their design. Forkert et al., (2021) report a follow-up length of one month, as did Sheaves et al., (2019), Serruya & Grant, (2009) had a follow-up length of one year. Pitfield et al., (2020) follow-up length was either two-week or three-weeks dependent upon participant baseline length.

Participants had a mean age of 36.97 years old, 64% (*n* =65) male, 36% (*n* =37) female. A range of schizophrenia-spectrum diagnoses were included, however, the majority of participants, 58% (*n*=59), were assessed as having, or reported a diagnosis of schizophrenia.

[TABLE 1 HERE]

Quality Appraisal

Quality appraisal scores from the CCAT (Crowe & Sheppard, 2011) are reported in Table 2, with scores out of five reported across all categories, a total score (max=40) and corresponding total percentage stated. There is no cut off to specify if papers were high, average, or low quality and no papers were excluded on the basis of quality, however, results and conclusions drawn have been weighted accordingly. Total percentages ranged from 33% (Serruya & Grant, 2009) to 88% (Sheaves et al., 2019), with a mean percentage score of 70.63%. All papers were independently scored by the first author. To improve the reliability of the quality appraisal, 25% of papers were independently rated by a colleague. Minor discrepancies were resolved using the manual and further consideration of the paper. Scores were then agreed by both appraisers.

Ethical matters, defined by the tool as encompassing ethical behaviour towards participants and by the researcher, were a shortcoming for many papers as they failed to report if and how informed consent was obtained or explicitly stated how participants' confidentiality and anonymity were maintained. Design and sampling categories also saw lower scores due to inadequate information on the validity, reliability and rationale for measures and interventions, alongside lack of information on sampling methods, why they were chosen and the suitability of these methods. A more general weakness was the lack of service user/patient involvement in the design of studies, with only one paper including experts by experience (Taylor et al., 2020). This potentially undermines the extent to which the research conducted to date is relevant to the needs of the population in which it is conducted (National Institute for Health Research, 2021). Confidence in the acceptability of psychometric measures and recruitment strategy is also reduced.

[TABLE 2 HERE]

Main Outcomes

Reported changes on measures of delusions

Seven of the included studies reported decreases in paranoia for people with psychosis with delusions following an imagery focused intervention. However, one study, Ascone et al., (2017) reported no specific interventions effects sizes regarding the reduction of paranoia for the group that received the compassion focused intervention. Nevertheless, there was an overall decrease in paranoia for participants irrespective of group allocation. Participants were randomised to a control imagery condition or compassion focused imagery condition and consisted of both inpatients and outpatients.

Morrison (2004), reported a case example of a participant experiencing persecutory delusions and intrusive images about people assaulting him. The participant engaged in a cognitive therapy assessment and verbal reattribution methods before participating in

fourteen sessions of cognitive therapy, with imagery-techniques implemented in session seven and eight. The remaining sessions focused on consolidation of gains. PSYRATS (Haddock et al., 1999) was used as a weekly measure of delusions throughout the intervention. Scores on conviction dropped from four to zero, and scores for preoccupation and distress fell from three to zero from initial to last session.

According to the PSYRATS user manual (Haddock, 2009) items scored as a four are beliefs that cause complete disruption of daily life, a score of three is given if beliefs cause severe disruption but the participant is able to maintain some daily activities or self-care, a zero is no disruption to life, able to maintain independent living with no problems. In session seven, when imagery technique was introduced, conviction was four, preoccupation and distress were three, and the following week all three of these items were rated as zero. Imagery was also said to be the focus of session eight and in session nine an increase in preoccupation and conviction of one point on each is reported. However, it is not clear if the PSYRATS was completed prior to the session or at the end. Furthermore, not all items of the PSYRATS delusions sub-scale are reported and remain unclear.

Similarly to Morrison (2004), Serruya & Grant, (2009) reported a single case where six guided imagery sessions were completed within a longer piece of therapy consisting of a total of 38 CBT sessions. At baseline the participant reported 100% conviction in persecutory delusions. Six-months later at the end of treatment delusion as scored by the PSYRATS delusion sub-scale had dropped from 17 to 14 and then to zero at 12-month follow-up. The authors reported that approximately 16% of the intervention used imagery techniques, with the majority of the intervention focused on other CBT techniques. It is therefore difficult to attribute improvement in the participants delusion solely to the use of imagery techniques.

The remaining studies used more methodologically rigorous designs with all six papers scoring above average in the quality appraisal tool , however, sample sizes were still

small and conclusions must be considered cautiously. Pitfield et al., (2020) reported that paranoia reduced for both participants in the two-person case series but was not maintained at follow-up. One participant completed a two-week baseline, whilst the other completed a three-week baseline. Both reported high and variable levels of paranoia. The intervention phase of one week required participants to listen to a personalised, guided imagery recording and complete measures daily. Ratings of paranoia reduced for both participants throughout the intervention, supporting the hypothesis that secure attachment imagery could reduce paranoia. However, paranoia scores increased again during the follow-up period. Other studies found reductions in paranoia could be maintained at follow-up. Forkert et al., (2021) conducted an uncontrolled feasibility trial that explored the impact of a single technique, self-compassionate imagery, for patients with persecutory delusions. Assessments of paranoia were completed before and after the four-session intervention, and again at one-month follow-up. Results indicated medium effect sizes in paranoia, which was maintained at follow-up.

Taylor et al., (2020) used a randomised multiple baseline case series design. Results indicated that three of five participants experienced reductions in paranoia, with two of them achieving much improved clinically significant change as rated by the PSYRATS delusion sub-scale.

The final two papers meeting inclusion criteria focused upon nightmares and imagery focused therapy to reduce the distress. Sheaves et al., (2015) conducted a case series of between four and six sessions of imagery rehearsal therapy with five participants. All participants experienced either persecutory or grandiose delusions. PSYRATS delusion score decreased for four of the five participants and increased for one; for two participants reductions in delusional beliefs were significant. Following the case series, a pilot RCT was conducted (Sheaves et al., 2019). Participants were successfully randomised to intervention

or treatment as usual conditions and assessments were blinded. The experimental condition experienced moderate reductions in paranoia compared with the control group which received treatment as usual. The intervention focused on imagery rescripting of nightmares and behavioural tests of persecutory beliefs were absent, however paranoia still reduced.

Reported changes on measures of imagery

Only one paper, Taylor et al., (2020) used psychometric measures to assess mental imagery. Intrusive images were reported to be compelling, absorbing, vivid and pre-occupying, as well as highly distressing. 'Much improved' clinically significant changes were reported for two participants, with a third experiencing a small decrease. The two remaining participants showed increase in scores. Imagery distress reduced by 50% between initial assessment and the final end-of-therapy assessment with a medium effect size (d=0.67).

Other papers reported changes of imagery anecdotally and were based on participants reporting which may be more likely to be biased by demand characteristics. Participants from the single case examples reportedly found certain imagery techniques most useful in reducing distress. One participant stated that a technique similar to traditional exposure techniques reduced their anxiety connected to the image from eight, to four out of 10 (Serruya & Grant, 2009). Another reported that manipulating the image and adding humour was most effective in reducing distress caused by the image (Morrison, 2004).

Secondary Outcomes

Acceptance and feasibility of interventions

Where data were available, studies appeared to be acceptable and feasible. For the two single case examples, participants engaged with the therapeutic interventions that contained imagery-focused techniques and no serious adverse events were reported (Morrison, 2004; Serruya & Grant, 2009). Pitfield et al., (2020) also reported no adverse events but further information on acceptability and feasibility was not available. A four-session compassionate

imagery intervention reported medium to large effect sizes on all clinical outcome measures and reported the intervention to be feasible and acceptable, with no adverse events reported (Forkert et al., 2021). Of all potential participants 86% gave consent to take part in the research. Throughout the intervention all sessions were attended, and all measures were completed.

Several studies also reported recruitment rates. In their case series, Sheaves et al., (2015) recruited from a group of participants from a previous study that experienced weekly nightmares (*n*=22). Of these 22, 20 agreed to be contacted with 18 meeting inclusion criteria. Seven participants were invited to take part and six consented. Taylor et al., (2020) reported that 62.5% of those eligible consented to participate. All participants exceeded the three-session attendance threshold that had been pre-set as a reasonable level of attendance and no participant withdrew during therapy. Ascone et al., (2017) asked 56 participants to participate with 51 being included in the final sample, a recruitment rate of 91.07%.

In their one-session, brief intervention, Ascone et al., (2017) reported that working with imagery in people experiencing paranoia was considered largely positive by participants. However, some adverse effects were reported such as increases in shame. Two patients who expressed high levels of mistrust withdrew from the study and further information on recruitment numbers is not available, therefore conclusions on feasibility cannot be made. Five of six participants completed all sessions of Sheaves et al., (2015) case series. One participant withdrew, stating that their nightmares had stopped occurring. The remaining participants continued to experience nightmares but noted reduced distress and an increased ability to cope. On average participants reported the satisfaction for intervention to be 9.2 out of 10. The randomised controlled trial that followed, reported 100% completion rates of therapy and similarly high therapy satisfaction rates (Sheaves et al., 2019).

Discussion

The primary aim of this review was to examine the outcomes of imagery focused interventions in people with psychosis and delusions. A secondary outcome of the review was to explore the acceptance and feasibility of imagery-focused interventions. Eight papers were included after a thorough systematic search following PRISMA guidelines. Both aims of the review were achieved. Regarding the primary aim, seven papers reported a decrease in paranoia following an imagery focused intervention. Ascone et al (2017) reported an overall decrease in paranoia irrespective of imagery condition, they had hypothesised that the compassion focused intervention would lead to larger therapeutic gains compared to a control imagery condition. Outcomes related to changes in imagery were more difficult to ascertain as only one paper (Taylor et al., 2020) measured mental imagery using psychometric measures. Both psychometric and anecdotal data indicated that imagery focused interventions had reduced the distress caused by intrusive images.

Regarding the secondary aim, from the available data, studies indicated that imagery-focused interventions are acceptable and feasible for people with psychosis who experience delusions. No adverse events were reported and recruitment and completion rates of the interventions were high across studies.

All eight papers included within this review reported reductions in paranoia following imagery intervention and suggest that such interventions are acceptable and feasible. However, there were a number of limitations in regard to each study which limited the conclusions which could be drawn. For example, in the Ascone et al. (2017) study, a reduction in delusions was not found as a group difference but overall, across both a compassionate imagery condition and control imagery condition. The authors hypothesised that the calm breathing baseline or soft tone of voice used in both conditions may have accounted for changes in both groups. Furthermore, this is the only sample to recruit

participants from both an inpatients and community setting which may have impacted results (Ascone et al., 2017). Both single case studies included, reported that the participant experienced a decrease in their delusional beliefs (Morrison, 2004; Serruya & Grant, 2009). The authors attribute this reduction, in part, to the use of imagery-focused techniques within a larger piece of cognitive therapy work. As noted, imagery was omnipresent in the development of cognitive and behavioural therapies (Edwards, 2007) and was employed in a range of therapeutic techniques (McEvoy et al., 2015). Both Morrison (2004) and Serruya and Grant (2009) clearly demonstrated how imagery focused techniques could be implemented within an extended piece of therapy. Although results from both case examples should be considered with caution given the methodological limitations and below average quality scores, which would make replication difficult and weakens the generalisability of results.

Another area to consider was if the reported reductions in delusions could be sustained beyond the intervention phase of research. Effects were maintained at one-month follow-up after a standalone compassionate imagery intervention (Forkert et al., 2021), however, in another study, both participants scores on delusion measures returned to baseline levels at follow-up (Pitfield et al., 2020). A follow-up of one year from baseline assessment saw a continued drop in delusions to a score of zero, however, as imagery was only part of the longer therapeutic intervention, its role in this reduction cannot be differentiated from other confounders (Serruya & Grant, 2009). Medium effect sizes one month after intervention were reported in Sheaves et al., (2019), with high follow-up rates of 83.33%. This overcame a limitation of Sheaves et al., (2015) as measures were not repeated at follow-up. Other studies were also limited by the lack of a follow-up period (Ascone et al., 2017; Morrison, 2004; Taylor et al., 2020). It appeared that reductions in delusions were maintained when the intervention actively involved the participant and therapist and was utilised as a

predominantly standalone therapeutic protocol. Paranoia scores in Pitfield et al., (2020) may have returned to baseline following intervention for a number of reasons. For example, the changeable and high levels of paranoia at baseline for both participants suggested a level of chronicity in their experience of delusions. It is important to note that one participant inadvertently reduced their follow-up period as they continued using the guided imagery recording longer than the stipulated timeframe due to forgetting to stop and finding the intervention useful. Given the hypothesis that attachment-based imagery may supplement trauma interventions for people with psychosis and persecutory delusions (Pitfield et al., 2020) and alleviate some clinician's distress about offering these interventions, further research into the feasibility of continued use is warranted.

Despite the small sample size, a range of psychosis-spectrum diagnoses were included, and some participants were reported to have experienced chronic and complex mental health problems. Given the therapeutic gains and limited adverse events, clinician's hesitancy about using imagery focused techniques with this population may be somewhat alleviated (Gairns et al., 2015; Sin et al., 2017). Furthermore, as reported in table two, a range of imagery techniques contributed to these therapeutic gains. The most prevalent imagery technique was imagery rescripting used by Sheaves et al., (2015, 2019) and Taylor et al., (2020). Ascone et al., (2017) and Forkert et al., (2021) both used compassionate imagery as the basis for their interventions. Pitfield et al., (2020) was the only study to use attachment based imagery and as previously reported Morrison (2004) and Serruya and Grant (2009) incorporated imagery techniques into cognitive therapy. This demonstrates that a range of imagery-focused interventions can be used within a sample of people with psychosis.

Methodological Considerations

The CCAT (Crowe & Sheppard, 2011) identified areas of strength within the included papers. There was clear reporting of aims and hypotheses, the inclusion of key information

and summary of current knowledge alongside clear rationales for the studies' focus. Discussion sections were also strong with clear summaries of findings that were further explored within the context of the available literature.

Most studies failed to report clear processes on ethical matters such as how informed consent was obtained and how confidentiality and privacy were maintained. These are particularly important to address given the clinical nature and vulnerable population studies were conducted with. Further weaknesses related to the lack of rationale for authors use of designs, measures and interventions, whilst sometimes addressed by stating the exploratory nature of the study, was frequently left to be assumed rather than explicitly stated. Finally, only one study reported the consultation of service users (Taylor et al., 2020). Service user involvement in research and healthcare has increased rapidly with multiple studies reporting benefits such as, service users greater sense of control over services they have received, improved care co-ordination and positive clinical outcomes (Laitila et al., 2018; Omeni et al., 2014). However, the service user voice is absent in the majority of research designs, methods and interventions that this review covers.

A variety of definitions of mental imagery exist and the debate regarding the nature of mental imagery has been long-standing (Thompson, 2007). Only one study, (Serruya & Grant, 2009), reported a definition of mental imagery. Further clarification and an agreement on a broad description of the experience we are trying to explore could only be useful. Alongside the lack of definitions is the absence of clear measures to quantify or describe a person's experience of mental imagery. No clear preference for an imagery assessment tool was evident, with only one paper reporting the use of imagery measures (Taylor et al., 2020). Without an understanding of the participants' propensity for mental imagery, the frequency of which they experience it and the characteristics of their imagery e.g., intrusiveness, vividness, emotional nature; it is difficult to compare and generalise findings however

positive they may seem. Measures of delusions also varied, however, four of the papers reported PSYRATS (Haddock et al., 1999) scores that allowed for comparison of the clinical severity of people's experiences.

General methodological weaknesses were the research designs and small number of participants. Only two RCTs, Ascone et al., (2017) and Sheaves et al., (2019), were included alongside several case series and two individual case presentations. It is important to understand the lack of more robust research designs in the context of the infancy of this research area. Furthermore, potential confounding variables were frequently unreported, for example medication use. Most studies did not control for demographic variables, Ascone et al., used a randomisation procedure that resulted in samples roughly equivalent to each other. Sheaves et al., also randomised participants and whilst gender was matched on both groups, other variables were not, e.g. ethnicity and diagnosis.

Strengths and Limitations

This is the first review that we are aware of to investigate studies of mental imagery and delusions. The inclusion criteria were kept purposefully broad, allowing papers to be included where participants had psychotic experiences but had not received official diagnoses. This broadness also pertained to research designs, with a range of designs included, allowing important findings to be discussed regardless of sample size and participant experience. This review forms a base for future research in this area and contributes to suggestions that a move from diagnostic based interventions, towards symptom or experience-based interventions may help alleviate distress for people transdiagnostically.

Limitations are similar to those found across systematic reviews (Garg et al., 2008). There is a risk, despite a rigorous search strategy, that studies have been unintentionally missed or excluded. This risk has been alleviated as much as possible by employing thorough scoping searches, the piloting of search terms and consultation with a librarian. Whilst small

sample sizes and case presentations were included in this review, publication bias may still have affected the results as these types of studies are less likely to be published. Finally, the heterogeneity of included research regarding the measures used, interventions delivered and settings makes it difficult to draw more firm conclusions.

Clinical Implications

This is a growing area of research and notwithstanding the limitations noted above, several potentially important clinical implications are noteworthy. Perhaps the most notable clinical implication that the included research provides is that people with a range of psychosis diagnoses can engage with imagery focused therapeutic interventions. The available information indicates there were limited adverse events as a direct result of imagery interventions which may alleviate some of the caution expressed by clinicians considering the use of imagery focused techniques within this population (Gairns et al., 2015).

Mental imagery was reported to be emotionally distressing by the recruited participants. Furthermore, it appeared to be widely experienced across diagnostic groups, genders and age, supporting the important findings of Morrison et al., (2002) and Schulze et al. (2013). Given the distressing nature of some participants' mental imagery, and its connection to their psychotic symptoms or previous trauma, it appears to be an important area for clinicians to assess and explore with their clients. Failure to assess for the presence of mental imagery may mean clinicians are missing opportunities to alleviate a distressing experience for people experiencing psychosis with delusions.

Future Directions

This area would benefit from greater consistency in the definition, reporting and assessment of mental imagery. This would allow for a more reliable and valid replication of methodologies as well as enhancing the comparability of data. Psychometric measures may play a role in this, for example the SUIS would allow researchers to compare their samples of

spontaneous use of imagery with other studies and consider its role in an intervention's success. Furthermore, existing research indicates a connection between mental imagery and emotion. It remains unclear the extent to which mental imagery plays a causal role in one's emotions, particularly within people with psychosis or those who experience psychotic symptoms. This requires further exploration. Initially qualitative research may offer a phenomenological understanding that could inform how research asks about emotions, or measures more specific emotions to minimise the ambiguity of distress.

The papers included in this review lay an important foundation for future research. Given the early stage of research in this area, case series designs, convenience sampling and unmatched control groups are suitable designs. However, future research would benefit from more RCTs as these are considered the most rigorous methodology (Akobeng, 2005) when considering the causal relationship between an intervention, such as imagery-focused therapy, and an outcome, e.g., reduction in delusions. Adequately powered samples and the matching of intervention and control groups on potential confounding variables e.g. age, gender, medication would further add to design rigor. Assessments completed by a researcher blind to group allocation completed at multiple time points would also be beneficial. Whilst establishing a stable baseline is difficult within a clinical sample, especially where symptoms such as delusions can be extremely distressing; it is invaluable when researching the impact of an intervention. Regarding design, longer follow-up periods with blinded assessors, would allow for the exploration of what interventions create lasting change. Another important consideration is the involvement of those with lived experience, in the conceptualisation, design and delivery of research interventions.

Finally, whilst results are promising despite the limitations discussed, it is important to consider whose experiences are missing from this body of research. Whilst not an aim of the review a brief exploration of the included studies demographics indicate that all but one

study, Morrison (2004), reported the ethnicity of their participants. However, no study considered the collected ethnicity data in their interpretation of results as suggested by Ross et al., (2020). Future research would benefit from consultation with Black African, Black Caribbean, South Asian, White Other and Mixed Ethnicity people. Racial inequality exists within mental health services (Koodun et al., 2021) and has been connected with worse social and service use outcomes for Black African and Black Caribbean service users with psychosis, compared to White British service users (Morgan et al., 2017). Therefore, it is paramount that research meaningfully includes these service users to ensure their voices and experiences are heard and considered within the development of new therapeutic interventions.

Conclusions

Despite a limited number of papers and their methodological limitations, it appears that imagery-focused interventions are tolerable and beneficial to people with psychosis and delusions. Whilst further research is needed to build upon these findings, there are clear and positive clinical implications. Mainly that it is possible to conduct research in populations of people with psychosis and delusions. This population is able to complete repeated measures about a range of experiences at baseline, intervention and follow-up. People with psychosis, who are help-seeking and able to consent to research, can try new therapeutic techniques delivered by therapists, researchers or via recording.

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Tables and Figures

Figure 1

PRISMA Flow Diagram

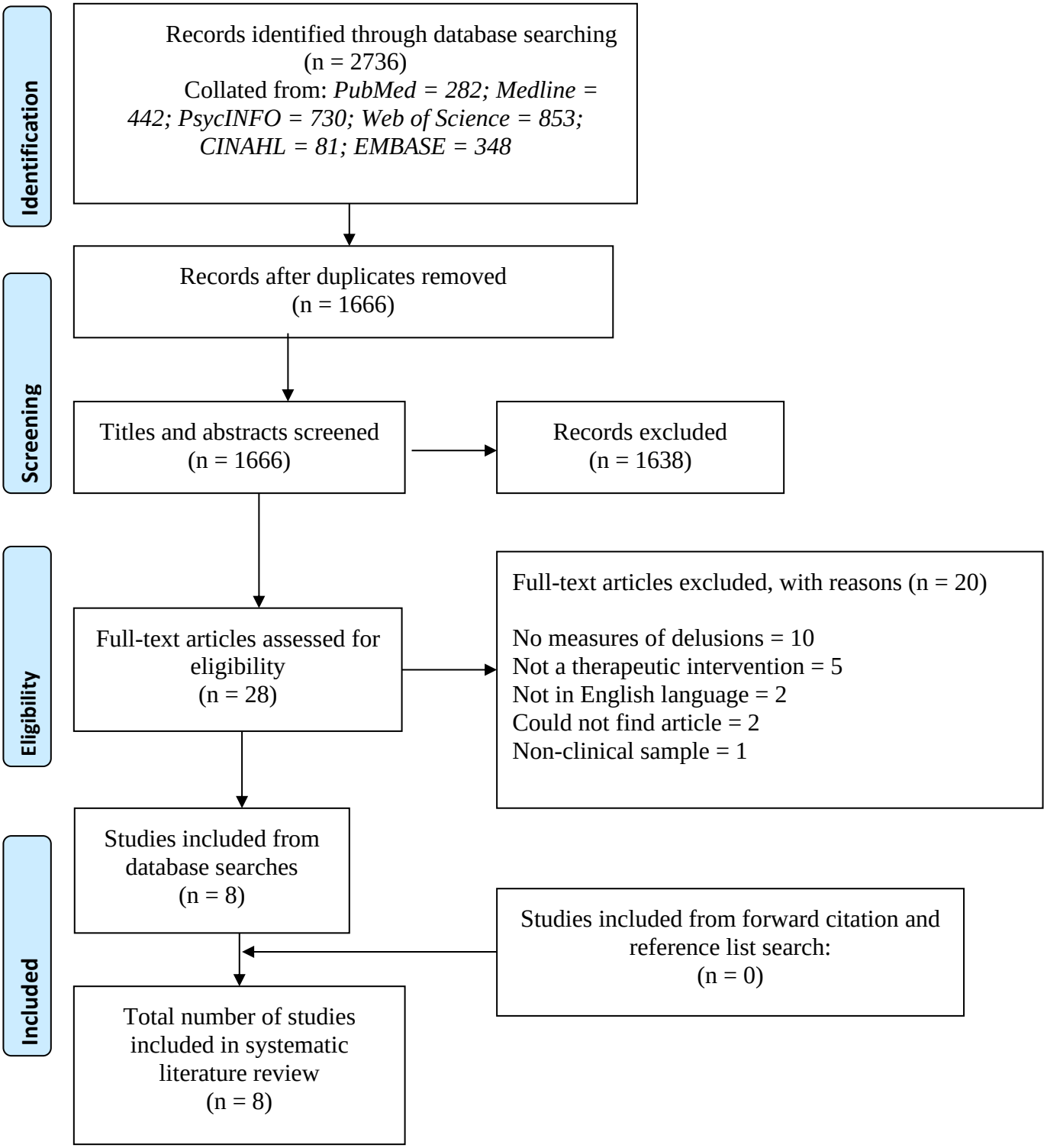

Table 1

Studies utilising an imagery focused intervention in a population of people with psychosis and delusions

Authors and Country	Diagnoses	Mean age (*SD*)	*N*	Sex	Design	Imagery intervention	Measures of Delusions	Other Measures	Results
Ascone et al., 2017 Germany	SZ = 34, SZ non-specified = 5, SA = 4, drug induced paranoid delusions = 2, BPA with psychotic symptoms = 1	Control group = 36.2 (10.1) Experimental group = 40.2 (12.9)	51	Control group; M=19, F=6 Experimental group; M=17, F=9	Repeated measures, randomised controlled design	Compassion focused imagery techniques (Gilbert, 2010)	18-PC	FSCRS; NaPA; SAM; S-CS; skin conductance levels	No group x time effect on paranoia (p=0.532). Significant main effect for time (p=0.017). Overall decreases in paranoid ideation independent of group allocation. No significant effect size found.
Forkert et al., 2021 UK	SZ = 9, FEP = 1, PNOS = 2	42 (13.1)	12	M=7, F=5	Uncontrolled feasibility study	Four-session compassionate imagery intervention (Gilbert, 2005, 2010; Kolts, 2012; Lee & James, 2011; K. Neff, 2011; Welford, 2012)	GPTS	BCSS; S-CS, SCS, RSE	Medium effect size, post-treatment in paranoia (change score 10.08, 95% CI 3.47, 16.69, d= 0.61) Improvements were maintained at follow-up
Morrison, 2004	DD = 1	30	1	M=1	Case example	Imagery techniques	PSYRATS	None	Preoccupation, conviction and distress as measured by

Authors and Country	Diagnoses	Mean age (*SD*)	*N*	Sex	Design	Imagery intervention	Measures of Delusions	Other Measures	Results
UK						within cognitive therapy (Ehlers & Clark, 2000; Hackmann, 1997)			PSYRATS delusions subscale all reduced. Preoccupation and distress reduced from 3 to 0, conviction reduced from 4 to 0.
Pitfield et al., 2020 UK	SZ = 2	52 (male), 49 (female)	2	M=1, F=1	A-B-A design with matched follow-up length	Attachment based guided imagery (Bullock et al., 2016)	GPTS; PC-5	PAM; PANAS	Variable levels of paranoia over baseline which reduced during intervention phase but returned to baseline scores at follow-up.
Serruya & Grant, 2009 USA	PSz = 1	25	1	M	Single case study	Imagery techniques within CBT therapy (Holmes et al., 2007)	PSYRATS	BAI; BDI-II; SANS	PSYRATS delusion at baseline, 17; at end of treatment (6months), 14; at follow-up (12 months), 0.
Sheaves et al., 2015	PSz = 3, SZ = 1, PNOS = 1, BPA =1	39.67 (12.53)	6	M=2, F=4	A-B case series	Imagery rescripting for nightmares (Nappi et al., 2010)	PSYRATS	DASS-21; Dream Log (Levin & Fireman, 2002); CORE-10; PDS; PPD; PSQI; VPD	PSYRATS delusion scores decreased for 4/5 participants. Baseline mean = 18.00(*SD*=1.87); post intervention mean = 16.20(*SD*=2.77).

Authors and Country	Diagnoses	Mean age (*SD*)	*N*	Sex	Design	Imagery intervention	Measures of Delusions	Other Measures	Results
Sheaves et al., 2019 UK	Experimental condition/ TAU condition SZ = 6/3, SA = 5/4, DD = 0/1, PNOS = 1/4	43/39	24	M=7/7, F=5/5	Parallel group pilot randomised control trial	Imagery rescripting for nightmares (Hackmann et al., 2011)	GPTS	BSS; CAPS; DASS-21, DDNSI; DES-B; SCI, PSQI, TBQ, WEMWBS	Experimental condition led to moderate reductions in paranoia at weeks 4 and 8 compared with TAU. Experimental condition/TAU Week 0 mean(SD) = 101.2 (35.7) / 109. 8(33.9) Week 4, mean(SD) = 75.3 (37.0)/109 (32.3), d=0.60 Week 8, mean(SD), 68.5(39.4)/100.7(35.5), d=0.54
Taylor et al., 2020 UK	SZ = 1, DD =1, SA =1, receiving care for FEP team = 2	23.40 (6.42)	5	M=3, F=2	Randomised multiple baseline case series	iMAPS Taylor et al (2019) practice guide	PANSS; PSYRATS	AEP; BCSS; CDSS, MIPQ; SMI; SUIS; YSQ-S; WAI-SR	PSYRATS delusions reduced, 16.60(0.89) at initial assessment, 15.80 (2.28) at last baseline, 8.25 (9.00) at end of treatment. Large effect size found, d=0.96. Scores for two participants suggested much improved clinically significant change. PANSS positive subscale decreased by 17.1%, a large effect size, *d*=1.45

Note: Diagnoses abbreviations: BPA = bipolar affective disorder; DD = delusional disorder; FEP = first episode psychosis; PNOS = psychosis not otherwise specified; PSz = paranoid schizophrenia; SA = schizoaffective disorder; SZ = schizophrenia, TAU = treatment as usual.

Sex abbreviations: F = female; M = male

Measures of delusions abbreviations: 18-PC = 18-item Paranoia Checklist (Freeman et al., 2005); GPTS = Green et al. Paranoid Thought Scales (Green et al., 2008); PANSS = Positive and Negative Syndrome Scale (Kay et al., 1987); PC-5 = Paranoia Checklist 5-item state version (Schlier et al., 2016); PSYRATS = Psychotic Symptom Rating Scales (Haddock et al., 1999);

Other Measures abbreviations: AEP = Adverse Effects in Psychotherapy (Hutton, 2016); BAI = Beck Anxiety Inventory (Beck et al., 1988); BCSS = Brief Core Schema Scale (Fowler et al., 2006); BDI-II = Beck Depression Inventory II = (Beck et al., 1996); BSS = Beck Suicide Scale (Beck et al., 1979); CAPS = Cardiff Anomalous Perceptions Scale (V. Bell et al., 2006); CDSS = Calgary Depression Rating Scale for Schizophrenia (Addington et al., 2014); CORE-10 = Clinical Outcomes in Routine Evaluation (Connell & Barkham, 2007); DASS-21 = Depression, Anxiety and Stress Scales (Lovibond & Lovibond, 1995); DDNSI = Disturbing Dream and Nightmare Severity Index (Krakow, 2006); DES-B = Brief Dissociative Experiences Scale (Dalenberg & Carlson, 2010) ; FSCRS = Forms of self-criticism and reassurance (Gilbert et al., 2004); MIPQ = Mental Imagery in Psychosis Questionnaire (adapted from Holmes et al., 2016); NaPA = Negative and Positive Affect (Stemmler et al., 2001); PANAS = Positive and Negative Affect Scale (D. Watson et al., 1988); PAM = Psychosis Attachment Measure (Berry et al., 2007); PDS = Posttraumatic Diagnostic Scale (Foa et al., 1997); PPD = Persecutor Power Differential (adapted from VPD; Birchwood et al., 2000); PSQI = Pittsburgh Sleep Quality Index (Buysse et al., 1989); RSE = Rosenberg Self-Esteem Scale (Rosenberg, 1965); SAM = Self-

Assessment Manikin (Bradley & Lang, 1994); SANS = (Andreasen, 1989); S-CS = Self-Compassion Scale (K. D. Neff, 2003); SCI = Sleep Condition Indicator (Espie et al., 2014) SCS = Social Comparison Scale (Allan & Gilbert, 1995; adapted by Freeman et al., 2014); SMI = Schema Mode Inventory (Lobbestael et al., 2010); SUIS = Spontaneous Use of Imagery Scale (Nelis et al., 2014); TBQ = Time Budget Questionnaire (Jolley et al., 2006); VPD = Voice Power Differential (Birchwood et al., 2000); WAI-SR = Working Alliance Inventory (Hatcher & Gillaspy, 2006); WEMWBS = Warwick-Edinburgh Mental Well-being Scale (Tennant et al., 2007); YSQ-S = Young Schema Questionnaire-Short Form (Young & Brown, 2003)

Table 2

Quality appraisal CCAT scores for included papers

Reference	Preliminaries	Introduction	Design	Sampling	Data Collection	Ethical Matters	Results	Discussion	Total Score	Corresponding total (%)
Ascone et al., 2017	4	3	5	4	5	3	3	4	31	78
Forkert et al., 2021	4	4	4	3	3	4	4	5	31	78
Morrison, 2004	3	3	2	1	2	1	2	2	16	40
Pitfield et al., 2020	5	4	4	4	3	5	4	4	33	83
Serruya & Grant, 2009	2	3	2	0	1	0	2	3	13	33
Sheaves et al., 2015	5	5	3	4	3	3	5	4	32	80
Sheaves et al., 2019	4	5	4	4	5	5	4	4	35	88
Taylor et al., 2020	5	5	4	4	4	4	4	4	34	85

Appendices

Appendix A: Psychology and Psychotherapy Author Guidelines

Aims and Scope

Psychology and Psychotherapy: Theory Research and Practice is an international scientific journal with a focus on the psychological aspects of mental health difficulties and well-being; and psychological problems and their psychological treatments. We welcome submissions from mental health professionals and researchers from all relevant professional backgrounds. The Journal welcomes submissions of original high quality empirical research and rigorous theoretical papers of any theoretical provenance provided they have a bearing upon vulnerability to, adjustment to, assessment of, and recovery (assisted or otherwise) from psychological disorders. Submission of systematic reviews and other research reports which support evidence-based practice are also welcomed, as are relevant high quality analogue studies and Registered Reports. The Journal thus aims to promote theoretical and research developments in the understanding of cognitive and emotional factors in psychological disorders, interpersonal attitudes, behaviour and relationships, and psychological therapies (including both process and outcome research) where mental health is concerned. Clinical or case studies will not normally be considered except where they illustrate particularly unusual forms of psychopathology or innovative forms of therapy and meet scientific criteria through appropriate use of single case experimental designs.

All papers published in *Psychology and Psychotherapy: Theory, Research and Practice* are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

Full details of publication can be found at:
https://bpspsychub.onlinelibrary.wiley.com/hub/journal/20448341/homepage/forauthors.html

Preparing the Submission

Free Format Submission

Psychology and Psychotherapy: Theory, Research and Practice now offers free format submission for a simplified and streamlined submission process.

Before you submit, you will need:

- Your manuscript: this can be a single file including text, figures, and tables, or separate files – whichever you prefer. All required sections should be contained in

your manuscript, including abstract, introduction, methods, results, and conclusions. Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision.

- The title page of the manuscript, including a data availability statement and your co-author details with affiliations. (Why is this important? We need to keep all co-authors informed of the outcome of the peer review process.) You may like to use this template for your title page.

Important: the journal operates a double-blind peer review policy. Please anonymise your manuscript and prepare a separate title page containing author details. (Why is this important? We need to uphold rigorous ethical standards for the research we consider for publication.)

- An ORCID ID, freely available at https://orcid.org. (Why is this important? Your article, if accepted and published, will be attached to your ORCID profile. Institutions and funders are increasingly requiring authors to have ORCID IDs.)

To submit, login at https://www.editorialmanager.com/paptrap/default.aspx and create a new submission. Follow the submission steps as required and submit the manuscript.

If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

Revised Manuscript Submission

Contributions must be typed in double spacing. All sheets must be numbered.

Cover letters are not mandatory; however, they may be supplied at the author's discretion. They should be pasted into the 'Comments' box in Editorial Manager.

Parts of the Manuscript

The manuscript should be submitted in separate files: title page; main text file; figures/tables; supporting information.

Title Page

You may like to use this template for your title page. The title page should contain:

- A short informative title containing the major key words. The title should not contain abbreviations (see Wiley's best practice SEO tips);
- A short running title of less than 40 characters;
- The full names of the authors;
- The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
- Abstract;
- Keywords;
- Data availability statement (see Data Sharing and Data Accessibility Policy);
- Acknowledgments.

Authorship

Please refer to the journal's Authorship policy in the Editorial Policies and Ethical Considerations section for details on author listing eligibility. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the Project CRediT website for a list of roles.

Abstract

Please provide an abstract of up to 250 words. Articles containing original scientific research should include the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use the headings: Purpose, Methods, Results, Conclusions.

Keywords

Please provide appropriate keywords.

Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

Practitioner Points

All articles must include Practitioner Points – these are 2-4 bullet point with the heading 'Practitioner Points'. They should briefly and clearly outline the relevance of your research to professional practice. (The Practitioner Points should be submitted in a separate file.)

Main Text File

As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors.

The main text file should be presented in the following order:

- Title
- Main text
- References
- Tables and figures (each complete with title and footnotes)
- Appendices (if relevant)

Supporting information should be supplied as separate files. Tables and figures can be included at the end of the main document or attached as separate files but they must be mentioned in the text.

- As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors. Please do not mention the authors' names or affiliations and always refer to any previous work in the third person.
- The journal uses British/US spelling; however, authors may submit using either option, as spelling of accepted papers is converted during the production process.

References

This journal uses APA reference style; as the journal offers Free Format submission, however, this is for information only and you do not need to format the references in your article. This will instead be taken care of by the typesetter.

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figures

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted.

Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Supporting Information

Supporting information is information that is not essential to the article, but provides greater depth and background. It is hosted online and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc.

Click here for Wiley's FAQs on supporting information.

Note: if data, scripts, or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points

For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association. The following points provide general advice on formatting and style.

- Language: Authors must avoid the use of sexist or any other discriminatory language.
- Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
- Units of measurement: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website for more information about SI units.
- Effect size: In normal circumstances, effect size should be incorporated.
- Numbers: numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Appendix B: PRISMA

Section and Topic	Item #	Checklist item	Location of item in report
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	

Section and Topic	Item #	Checklist item	Location of item in report
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix C: Database Search Terms

Database	Search
PubMed	((((Psychosis) OR (schizophreni*)) OR (delusion*)) OR ("psychotic disorder")) AND (((imagery) OR ("mental image*")) OR (mental (N) image*)) NOT (FMRI OR functional magnetic resonance OR brain imaging)
Medline	(psychosis OR schizophreni* OR delusion* OR psychotic disorder) AND (imagery OR "mental image*" OR mental (N) image*) S1 AND S2) NOT (fmri or functional magnetic resonance imaging or brain imaging or neuroimaging) Boolean/phrase
PsycINFO	(psychosis OR schizophreni* OR delusion* OR "psychotic disorder") AND (imagery OR "mental imag*" OR mental (N) image*) - S2 and S4 NOT (fmri or functional magnetic resonance imaging or brain imaging or neuroimaging - Search modes: Boolean/phrase
Web of Science	(((ALL=(psychosis)) OR ALL=(schizophreni*)) OR ALL=(delusion*)) OR ALL=("psychotic disorder") AND ((ALL=(imagery)) OR ALL=("mental image*")) OR ALL=(mental (N) image*) NOT ((ALL=(FMRI)) OR ALL=(functional magnetic resonance imaging OR "brain imaging")) OR ALL=(neuroimaging)
CINAHL	(psychosis OR schizophreni* OR delusion* OR "psychotic disorder") AND (imagery OR "mental imag*" OR mental (N) image*) S1 AND S2) NOT (fmri or functional magnetic resonance imaging or brain imaging or neuroimaging) Boolean/phrase
EMBASE	(psychosis OR schizophreni* OR delusion* OR "psychotic disorder") AND (imagery OR "mental NEAR/3 imag*) (((psychosis or schizophreni* or delusion* or "psychotic disorder") and (imagery or mental NEAR imag*)) not FMRI not functional magnetic resonance not neuroimaging)

Appendix D: Crowe Critical Appraisal Tool

Research design (add if not listed)		
❑ Descriptive, Exploratory, Observational		A. Cross-sectional | Longitudinal | Retrospective | Prospective | Correlational | Predictive | …
		B. Cohort | Case-control | Survey | Developmental | Normative | Case study | …
❑ Experimental	❑ True experiment	Pre-test/post-test control group | Solomon four-group | Post-test only control group | Randomised two-factor | Placebo controlled trial | …
	❑ Quasi-experiment	Post-test only | Non-equivalent control group | Counter balanced *(cross-over)* | Multiple time series | Separate sample pre-test post-test [no Control] [Control] | …
	❑ Single	One-shot experimental *(case study)* | Simple time series | One group pre-test/post-test | Interactive | Multiple baseline | system Within subjects *(Equivalent time, repeated measures, multiple treatment)* | …
❑ Synthesis		Systematic review | Critical review | Thematic synthesis | Meta-ethnography | Narrative synthesis | …
❑ Other		…

Variables and analysis		
Intervention(s), Treatment(s), Exposure(s)	Outcome(s), Output(s), Predictor(s), Measure(s)	Data analysis method(s)

Sampling									
otal size		roup 1		roup 2		roup 3		roup 4		ontrol	
Population, sample, setting									

Data collection (add if not listed)	
a) Primary | Secondary | … Audit/Review b) Authoritative | Partisan | Antagonist | … c) Literature | Systematic | …	a) Formal | Informal | … Interview b) Structured | Semi-structured | Unstructured | … c) One-on-one | Group | Multiple | Self-administered | …
a) Participant | Non-participant | … Observation b) Structured | Semi-structured | Unstructured | … c) Covert | Candid | …	a) Standardised | Norm-ref | Criterion-ref | Ipsative | … Testing b) Objective | Subjective | … c) One-on-one | Group | Self-administered | …

Scores

Prelimi naries		Design		Data Collection		Results		Total [/40]	
Introdu ction		Samplin g		Ethical Matters		Discuss ion		Total [%]	

General notes

Category Item	Item descriptors [❒ Present; ✍ Absent; ■Not applicable]	Description [Important information for each item]	core 0–5]
1. Preliminaries			
Title	1. Includes study aims ❑and design ❑		
Abstract (assess last)	1. Key information ❑ 2. Balanced ❑and informative ❑		
Text (assess last)	1. Sufficient detail others could reproduce ❑ 2. Clear/concise writing ❑,table(s) ❑,diagram(s) ❑,figure(s) ❑		
		Preliminaries [/5]	
2. Introduction			
Background	1. Summary of current knowledge ❑ 2. Specific problem(s) addressed ❑and reason(s) for addressing ❑	1.	
Objective	1. Primary objective(s), hypothesis(es), or aim(s) ❑ 2. Secondary question(s) ❑		
	Is it worth continuing?	**Introduction [/5]**	
3. Design			
Research design	1. Research design(s) chosen ❑and why ❑ 2. Suitability of research design(s) ❑		
Intervention, Treatment, Exposure	1. Intervention(s)/treatment(s)/exposure(s) chosen ❑and why ❑ 2. Precise details of the intervention(s)/treatment(s)/exposure(s) ❑for each group ❑ 3. Intervention(s)/treatment(s)/exposure(s) valid ❑and reliable ❑		
Outcome, Output, Predictor, Measure	1. Outcome(s)/output(s)/predictor(s)/measure(s) chosen ❑and why ❑ 2. Clearly define outcome(s)/output(s)/predictor(s)/measure(s) ❑ 3. Outcome(s)/output(s)/predictor(s)/measure(s) valid ❑and reliable ❑		
Bias, etc	1. Potential bias ❑,confounding variables ❑,effect modifiers ❑,interactions ❑ 2. Sequence generation ❑,group allocation ❑,group balance ❑,and by whom ❑ 3. Equivalent treatment of participants/cases/groups ❑		
	Is it worth continuing?	**Design [/5]**	
4. Sampling			
Sampling method	1. Sampling method(s) chosen ❑and why ❑ 2. Suitability of sampling method ❑		
Sample size	1. Sample size ❑,how chosen ❑,and why ❑ 2. Suitability of sample size ❑		
Sampling protocol	1. Target/actual/sample population(s): description ❑and suitability ❑ 2. Participants/cases/groups: inclusion ❑and exclusion ❑criteria 3. Recruitment of participants/cases/groups ❑		
	Is it worth continuing?	**Sampling [/5]**	
5. Data collection			
Collection method	1. Collection method(s) chosen ❑and why ❑ 2. Suitability of collection method(s) ❑		
Collection protocol	1. Include date(s) ❑,location(s) ❑,setting(s) ❑,personnel ❑,materials ❑,processes ❑ 2. Method(s) to ensure/enhance quality of measurement/instrumentation ❑ 3. Manage non-participation ❑,withdrawal ❑,incomplete/lost data ❑		
	Is it worth continuing?	**Data collection [/5]**	
6. Ethical matters			
Participant ethics	1. Informed consent ❑,equity ❑ 2. Privacy ❑,confidentiality/anonymity ❑		
Researcher ethics	1. Ethical approval ❑,funding ❑,conflict(s) of interest ❑ 2. Subjectivities ❑,relationship(s) with participants/cases ❑		
	Is it worth continuing?	**Ethical matters [/5]**	

7. Results		
Analysis, Integration, Interpretation method	1. A.I.I. method(s) for primary outcome(s)/output(s)/predictor(s) chosen ❑and why ❑ 2. Additional A.I.I. methods (e.g. subgroup analysis) chosen ❑and why ❑ 3. Suitability of analysis/integration/interpretation method(s) ❑	
Essential analysis	1. Flow of participants/cases/groups through each stage of research ❑ 2. Demographic and other characteristics of participants/cases/groups ❑ 3. Analyse raw data ❑,response rate ❑,non-participation/withdrawal/incomplete/lost data ❑	
Outcome, Output, Predictor analysis	1. Summary of results ❑and precision ❑for each outcome/output/predictor/measure 2. Consideration of benefits/harms ❑,unexpected results ❑,problems/failures ❑ 3. Description of outlying data (e.g. diverse cases, adverse effects, minor themes) ❑	
		Results [/5]

8. Discussion		
Interpretation	1. Interpretation of results in the context of current evidence ❑and objectives ❑ 2. Draw inferences consistent with the strength of the data ❑ 3. Consideration of alternative explanations for observed results ❑ 4. Account for bias ❑,confounding/effect modifiers/interactions/imprecision ❑	
Generalisation	1. Consideration of overall practical usefulness of the study ❑ 2. Description of generalisability (external validity) of the study ❑	
Concluding remarks	1. Highlight study's particular strengths ❑ 2. Suggest steps that may improve future results (e.g. limitations) ❑ 3. Suggest further studies ❑	
		Discussion [/5]

9. Total		
Total score	1. Add all scores for categories 1–8	**Total [/40]**

Section Two: Empirical Paper

Telehealth delivered iMAgery focused therapy for delusions in PSychosis (iMAPS): A Case Series.

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Abstract: 209 words

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Abstract

Objectives: To examine the feasibility and acceptability of a telehealth imagery-based therapeutic intervention for people experiencing persecutory delusions. Based on a multiple baseline case series exploring imagery focused psychological therapy for persecutory delusions in psychosis (iMAPS).

Design: A non-concurrent A-B multiple baseline design was used.

Methods: Participants experiencing persecutory delusions and self-reporting a psychosis or schizophrenia-spectrum diagnosis were recruited through online adverts. They were randomly assigned to multiple baseline assessments, of between three and five sessions. Six therapy sessions followed, consisting of imagery formulation, safe place imagery creation, compassionate imagery, imagery manipulation and rescripting. Participants completed pre and post measures and sessional measures via an online survey software or in semi-structured interviews. Two weeks post-intervention, a final measure was completed exploring any potential adverse effects of psychotherapy.

Results: Five participants, all females, completed all baseline and therapeutic sessions. Results indicate strong effect sizes across PANSS positive subscale and mood, as well as participants reporting a clinically significant change in at least one measure e.g. PSYRATS. All participants reported a reduction in the realness and compelling nature of distressing imagery.

Conclusions: Results suggest delivering a telehealth imagery focused therapy is acceptable and feasibly delivered via telehealth. A control group and blinding of assessments would strengthen the methodological limitations present.

Keywords: psychosis, mental imagery, imagery, schizophrenia, case series, imagery-intervention

Telehealth delivered iMAgery focused therapy for delusions in PSychosis (iMAPS): A Case Series.

Introduction

Psychosis can describe a variety of experiences such as delusional thinking, hallucinations and anhedonia, typically experienced on a spectrum of severity (Freeman, 2016). Given the variety of symptoms and wide-ranging experiences within these, research has moved towards exploring and understanding individual psychotic experiences, rather than the diagnosis as a whole (Garety & Freeman, 2013). Paranoia, like other symptoms, is experienced on a spectrum. It is evident in the general population and can include feelings of mistrust, suspiciousness and ideas of reference (Freeman, 2007). Persecutory delusions are at the most severe end of the paranoia spectrum and are the unsubstantiated belief that others intend to cause harm. The belief is strongly held with at least 50% conviction, beliefs also cause distress and impairment (Freeman, 2016). Persecutory delusions can lead to the person feeling unsafe, emotionally distressed and socially withdrawn. They are commonly experienced and frequently acted upon, for example, people who feel threatened may try to prevent a feared catastrophe by using a safety behaviour such as avoidance (Freeman, Garety, et al., 2007). Such beliefs are typically experienced alongside depression (Vorontsova et al., 2013), anxiety (Hartley et al., 2013), poor physical health and suicidal ideation (Freeman et al., 2011). Of those who experience persecutory delusions, as many as 50% experience levels of psychological wellbeing within the lowest 2% of the general population (Freeman et al., 2014).

To improve psychological wellbeing for this group, research that explores factors linked to distress could be useful. Several clinical populations report experiences of negative, distressing mental imagery that impacts their emotional wellbeing (Brewin et al., 2010; Harvey et al., 2004). Mental imagery is described as a perceptual experience that can be

consciously experienced and involve any of the sensory modalities (Ji et al., 2019). Research in bipolar disorder suggests that imagery may act as an "emotional amplifier" (Holmes & Mathews, 2010, p. 353), further research is needed to investigate this within psychosis. Two publications have found that intrusive mental imagery is widely experienced within a population of people with psychosis and persecutory delusions. Morrison et al., (2002) reported that 74% (n=26) of participants with psychosis experienced images related to their hallucinations and delusions. Eleven years later these results were replicated, with research indicating 72.5% (n=29) of participants experienced intrusive images associated with psychotic symptoms and persecutory delusions (Schulze et al., 2013). In both studies, participants described images as negative, anxiety-provoking and highly distressing with imagery content linked to feared catastrophes associated with persecutory beliefs and traumatic memories.

Within the UK, guidance remains focused on diagnostic categories, as such, the National Institute for Health and Care Excellence (NICE, 2015) recommend Cognitive Behavioural Therapy (CBT) for people with psychosis. Imagery has played a role in CBT throughout its history, although clinicians can be hesitant to incorporate imagery into interventions. Newly qualified CBT therapists reported lacking confidence in imagery techniques and concerns that imagery may increase affect and be destabilising (Bell et al., 2015). Despite this hesitancy, the CBT therapists unanimously placed value on imagery and the strong rationale for using imagery techniques in therapy (Bell et al., 2015). Furthermore, there has been a growing interest in imagery techniques as a therapeutic tool across diagnoses (Blackwell, 2021).

Imagery-based Interventions

Imagery techniques have shown effectiveness for people experiencing depression (Brewin et al., 2010), social anxiety (Norton & Abbott, 2016) and self-harm (Di Simplicio et

al., 2020). They can be applied in a range of ways; imagery rescripting (Arntz, 2012), safe place imagery (Hackmann et al., 2011) and metaphorical imagery for facilitating emotional coping (Saulsman et al., 2019).

Imagery rescripting is potentially the most prevalent technique and involves the client recalling a selected memory or intrusive image. Then, with the clinician, the memory or image is modified to a safer one e.g. changing the ending. By altering the meaning of the image, emotions associated are also changed (Paulik et al., 2021). Research suggests its effectiveness as a therapeutic technique across clinical presentations e.g. obsessive-compulsive disorder (OCD; Maloney et al., 2019); eating disorders (Tatham, 2011) and social anxiety disorder (Lloyd & Marczak, 2022). However, it was initially developed for use in posttraumatic stress disorder (PTSD; Smucker et al., 1995). Within psychosis, the lifetime prevalence of PTSD is estimated to be 30% (Hardy & Mueser, 2017). In a student sample reporting high levels of paranoia, a single session of imagery rescripting resulted in reduced distress and emotional intensity. Despite the lack of a control group, large effect sizes suggest that people who experience paranoia can tolerate imagery rescripting and benefit from it (Newman-Taylor et al., 2018). In a sample of people with psychosis, who also met the criteria for PTSD on a self-report measure, imagery rescripting for self-referential appraisals was found to be highly acceptable (Clarke et al., 2021). Results were promising; appraisal conviction and distress significantly reduced, alongside clinically significant change in PTSD symptoms being experienced by most participants.

Given the usefulness of imagery on problems that are comorbidly experienced within a psychosis population (Buckley et al., 2009), research moved to explore its effectiveness regarding psychotic symptoms. A case example with a 30-year-old male experiencing paranoid thoughts and persecutory delusions, whilst not methodologically rigorous, was the first to indicate that targeting intrusive images was feasible in the context of CBT.

Furthermore, it indicated that through imagery manipulation and development of a safe image, the participant's paranoia, distress and conviction in beliefs were reduced (Morrison, 2004). Similar findings were also reported in another case example where imagery techniques were used within a 38-session CBT intervention (Serruya & Grant, 2009). Both cases are largely limited by the lack of clear pre- and post-measures and the absence of baselines and control groups. A controlled group study addressed some of these weaknesses. Participants with schizophrenia listened to a guided imagery recording and reported improvements in measures of daily life skills, health and treatment function and general function. Despite employing a more robust design, information on data collection and design was lacking, limiting the generalisability of the results (Elgit, 2020).

A small number of studies have been conducted with more robust methodologies. A randomised experimental pilot study found that a single session of compassion focused imagery increased happiness and self-reassurance in a sample consisting of inpatients and outpatients (n=51) with psychosis-type diagnoses (Ascone et al., 2017). Forkert et al., (2021) delivered a four-session compassionate imagery intervention that was found to be feasible and acceptable and resulted in improvements across all outcome measures, including paranoia, with effects maintained at follow-up. In a similar clinical sample, a brief imagery rescripting protocol was reported to be feasible, safe and acceptable for people with psychosis. Participants reported significant reductions in appraisal conviction, distress and frequency of trauma memories (Clarke et al., 2021). All studies were conducted in samples with schizophrenia spectrum diagnoses. However, as previously described, people's experiences within diagnostic categories vary greatly. Taylor et al., (2020) used a robust methodological design within a sample of people with psychosis and persecutory delusions. Five participants were randomised to multiple baselines and took part in six sessions of therapy involving imagery techniques. Three participants reported benefits, two of whom

experienced clinically significant reduction in delusions and imagery distress. Noteworthy, was the significant reductions in negative schematic beliefs, as schemas in people with psychosis have been linked with distress and reduced social functioning (Taylor & Harper, 2017). Given that schemas are thought to be stable (Beck, 2020) and previous interventions in other severe mental health conditions have had long therapy windows (e.g. 50 sessions for patients with cluster C personality disorder diagnoses; Bamelis et al., 2014) change in these long-lasting core beliefs within six sessions is substantial. Overall, these papers suggest that imagery-based interventions are acceptable, feasible and safe within a population of people with schizophrenia spectrum diagnoses more broadly and for people experiencing specific distressing symptoms such as persecutory delusions. Whilst these results are promising there is a need to continue the development of innovative practices, this became particularly clear throughout the global pandemic, Coronavirus-19 (COVID-19, SARS-CoV-2, World Health Organisation [WHO], 2022).

Imagery focused therapy for psychosis and COVID-19

The expansion of digital services for effective care in mental health was included in the "Five Year Forward View of Mental Health" (NHS England, 2014). Research highlights that psychological treatments cannot meet the global demands for mental health support (van Os et al., 2019). There is a need for brief, efficacious, low-cost and flexible interventions (Singh et al., 2020), that are also person-centred and informed by formulation. Taylor, Bee, et al., (2019) introduced an approach informed by a qualitative study of core beliefs in people with psychosis (Taylor, Haddock, et al., 2019), CBT imagery manual (Hackmann et al., 2011), adapted imagery formulation model (Hales et al., 2014) and the authors' clinical experience. Within this publication, Taylor, Bee, et al., (2019) presented a detailed intervention guide of the formulation-based approach, which included techniques such as image suppression, behavioural experiments, manipulation of images, imagery rescripting of

past events and future flash-forwards and the creation of positive imagery. As previously stated, this approach led to a significant reduction in delusions and imagery distress for two participants, with three reporting clear benefits.

Prior to COVID-19, CBT was already frequently delivered remotely through web-based platforms (Gottlieb et al., 2013) with one-fifth of publicly-funded adult primary mental health provisions being telephone-based (Irvine et al., 2020). However, the national lockdowns implemented in response to COVID-19 across the UK and around the globe, appear to have led to an accelerated shift towards remote healthcare and delivery of mental health care and interventions via telehealth. For example, in Australia, during the first eight months of the pandemic, registrations for online CBT programmes increased by 504% (Mahoney et al., 2021). One mental health NHS trust in England reported a 298% increase in the uptake of remote consultations in adults of working age (18-65 years old; Patel et al., 2021).

COVID-19 led to stress, self-isolation, physical distancing and adverse psychological effects such as fear and anxiety for millions of people (O'Connor et al., 2021; Smith et al., 2020). Extensive research has identified stressful life events, alongside other psychosocial factors, as significant risk factors for the onset and exacerbation of psychotic symptoms (Fusar-Poli et al., 2017). It is well documented that people with a diagnosis of severe mental illness, such as psychosis, are disproportionately affected during public health disasters (Brown et al., 2020). Social isolation, unemployment and homelessness increased throughout the pandemic and may have affected people with psychosis given their vulnerability to social determinants impacting health (Anglin et al., 2020).

A scoping review assessed the feasibility and acceptability of interventions delivered via telehealth compared to face-to-face interventions for people with a diagnosis of schizophrenia spectrum disorder (Santesteban-Echarri et al., 2020). Fourteen studies (*n*=439)

reported that videoconferencing was feasible. Six studies found high levels of satisfaction and acceptance, with one reporting a strong preference for videoconferencing over waiting for and/or travelling to a psychiatric session. The conclusions drawn are limited by the poor quality of the included research. Clearly, a diagnosis of schizophrenia or the presence of delusional beliefs would not preclude people from engaging in telehealth-based interventions.

Building on existing literature and incorporating learning from the experiences of clinicians and clients (Paulik et al., 2021), might allow for the development of innovative practices that focus on single-core clinical features, such as persecutory delusions. Within populations experiencing persecutory delusions, telehealth interventions may provide another avenue for people to access services. Research indicates that social environments can be anxiety-provoking for people with persecutory delusions due to the fear of harm occurring. Consequently, they can avoid going out in public or to busy places thus minimising feelings of threat and anxiety (Freeman, Pugh, et al., 2007). By offering therapeutic interventions via telehealth, people may be better able to attend sessions and meaningfully engage in therapy.

Aims

This study aimed to formally test the feasibility and acceptability of an imagery-focused approach via telehealth for individuals who self-report persecutory delusions and experience intrusive images.

Research Questions

Our questions were: 1) is it possible to recruit participants to a telehealth case series? 2) How many participants drop out of the intervention? 3) What percentage of sessions offered were completed? 4) What are the reasons for participant drop out if they are willing to report? 5) Were there any serious adverse events or adverse effects (adverse effects were determined on a case-by-case basis)? 6) Does the intervention reduce a general rating of distress caused by images? 7) What do participants feedback about the intervention?

Method

Design

A telehealth case series was conducted using a non-concurrent A-B multiple baseline design, adapted from Taylor et al., (2020). A case series design is recommended by the Medical Research Council as one stage in developing more complex interventions (Skivington et al., 2021). A detailed overview of session content can be found in Taylor, Bee, et al., (2019). Table 1 details the intervention stages and their content, as well as measures that were completed at each point. These are explained in further detail below. All sessions were conducted by a third-year trainee clinical psychologist (AC), with weekly supervision from clinical psychologists (JK and CT). Sessions were recorded with informed consent. Sections were reviewed during clinical supervision, with reference to the Manual of the Revised Cognitive Therapy Scale (CTS-R, Blackburn et al., 2018). They were also reviewed to ensure the therapy offered, followed the assessment, formulation and interventions outlined in Taylor, Bee, et al., (2019). AC received training in iMAPS, CBT for psychosis and imagery manipulation/rescripting techniques. Ethical approval was obtained from Lancaster University's Faculty of Health and Medicine Research Ethics Committee (FHMREC20178, Appendix A) before the study commenced. The study was conducted in line with the principles of Good Clinical Practice (GCP; Health Research Authority, 2022) and the Declaration of Helsinki (World Medical Association, 2013).

Inclusion and Exclusion Criteria

Participants were eligible for inclusion if they: currently, or recently (within the past month) self-reported experiencing a persecutory delusion, could identify a distressing mental image related to this delusion and found their reported suspicious beliefs distressing. Inclusion criteria were: 1) aged 18-65 years old; 2) have capacity to provide informed consent; 3) a self-reported International Statistical Classification of Diseases and Related

Health Problems (10th ed., ICD-10 or 11th ed., ICD-11; WHO, 2019) diagnosis of psychosis, schizophrenia or schizoaffective disorder; 4) a current persecutory delusion meeting criteria outlined by Freeman and Garety, (2000; the individual believes that harm is occurring or is going to occur to them and the persecutor has the intention to cause harm); 5) able to identify a distressing image related to a persecutory delusion; 6) find their reported paranoid beliefs distressing or be help-seeking for paranoid or suspicious beliefs; 7) able to complete measures and the intervention in English; 8) able to access a device and internet connection to access video-conferencing software (e.g. Teams or Zoom), as well as a private space where they felt safe, were required.

Exclusion criteria included participants with a moderate/severe learning disability, acquired brain injury or neurological impairment, severe substance misuse that impaired their ability to engage with the study, an acute episode requiring in-patient care, participation in other treatment studies or currently receiving other psychological therapy.

Feasibility and Acceptability

Feasibility and acceptability were assessed by measuring participant flow throughout the study. The first four the research questions are answered using the following information. Recruitment rate and participant flow were measured by the number of potential participants who showed interest in taking part, the number of participants screened for eligibility and number of those eligible who consented or declined. Information regarding attendance at sessions, Did Not Attend or Could Not Attend rates and reasonable attendance (set at ≥ 3 sessions, out of 6-session intervention, in line with Taylor et al. [2020]) was also collected. Furthermore, participants who dropped out of the study at any point would be asked to provide reasons if they felt able to.

Therapeutic alliance was measured at two time points by both the researcher and participants, large discrepancies were considered poor, as stated in Hatcher & Gillaspy

(2006). Adverse effects such as participants reporting a worsening of symptoms following therapy were considered on an individual basis. Data from the measures detailed below aimed to answer the remaining three research questions.

Measures

Baseline and Intervention Measures

These measures were completed at each randomised baseline session (n = 3-5) and prior to each therapeutic intervention session (n = 6).

Psychotic Symptom Rating Scales (PSYRATS; Haddock et al., 1999). The PSYRAYS is a semi-structured multi-dimensional interview of delusions and hallucinations, therefore allowing the exploration of change across multiple dimensions e.g. frequency, which provides a detailed index of change on the target problem of delusions. Semi-structured interviews were used to assess the personal characteristics of hallucinations and delusions. The delusional subscale consists of six items e.g. amount of preoccupation. All items are rated based on the previous week, apart from conviction which is based on conviction at time of interview. The hallucination subscale rates over 11 dimensions e.g. frequency and intensity of distress. The majority of items are rated based on the participant's experience over the last week, within the hallucination subscale, beliefs about origin of voices and loudness of voice are rated based on participant's experience at time of interview. The scales have good inter-rater reliability and validity in chronic schizophrenia and first episode psychosis and suggested to be more sensitive to change, therefore reducing the risk of type-two error (Drake et al., 2007).

Mental Imagery in Psychosis Questionnaire (MIPQ; Taylor, Bee, et al., 2019), adapted from Holmes et al., 2016) The MIPQ contains five questions that explore characteristics of a person's mental imagery which this study is particularly interested in. It has been used in two previous studies, one in a sample of people with bipolar disorder (Holmes et al., 2016) and in

psychosis (Taylor et al., 2020) and appeared to be feasible. This measure captures characteristics of imagery that may be problematic for people and is sensitive to change. An additional two questions ask about the impact of the image on mood and the images helpfulness. Answers are rated on a 10-point Likert scale from 1, not at all, to 10, extremely. Internal consistency of the MIPQ was reportedly good ($\alpha = 0.90$) (Taylor, 2017).

Sessional Mood Rating. Participants were asked, "how would you rate your mood today, with zero being the worst it has ever been and 10 being the best?" at each session. Sessional mood provides an indication of how therapy is progressing and if a significant drop or low mood score is identified can prompt a risk assessment and/ or a focus on mood in the session.

Pre- and Post-Intervention Measures

These measures were completed at initial baseline and final therapeutic session.

Positive and Negative Syndrome Scale, *positive subscale* (PANSS; Kay et al., 1987). PANSS is a widely used clinical interview to assess the symptoms of schizophrenia. The positive subscale consists of 7-items and has high internal reliability, $\alpha = 0.80$ (Kay et al., 1989). When tested within a sample of 100 people with schizophrenia the PANSS had good interrater reliability, high concurrent validity and scores were normally distributed (Peralta and Cuesta 1994). Furthermore, the positive subscale had modest internal consistency, indicating it is comprised of several independent components. The PANSS positive subscale provides dimensional assessment using clear criteria improving the replicability of observations making it suitable as a pre- and post-intervention measure to assess for change across positive symptoms. AC received training on the PANSS positive subscale and access to a detailed scoring manual and supervision.

The Calgary Depression Rating Scale for Schizophrenia (CDSS; Addington et al., 2014). The CDSS is a clinical interview of nine items used to assess depression in people with schizophrenia, psychosis or psychotic-like experiences. Participants respond by indicating if a

symptom e.g. hopelessness, was absent, mild, moderate, or severe on an ordinal scale. Internal reliability in a sample of 150 patients with schizophrenia was good (α = 0.79; Addington et al., 1994). More recently, Monsonet et al., (2022) found the CDSS to be a reliable and valid measure of depression across schizophrenia diagnoses. A strength of this scale is that it distinguishes between negative symptoms of psychosis and depression. Furthermore, when compared to other depression rating scales the CDSS has been found to be a more specific measurement of depressive symptoms within a population of people with schizophrenia-spectrum disorders (Schennach et al., 2012).

Spontaneous Use of Imagery Scale (SUIS, Reisberg et al., 2003). The SUIS is a self-report scale of 12-items that measures spontaneous use of mental imagery in a person's daily life. The SUIS was reported to have good convergent validity and acceptable internal consistency (α = 0.72-0.76; Nelis et al., 2014) In a sample of 44 participants with first episode psychosis the SUIS was found to have acceptable reliability (α = 0.77; Smith et al., 2022). Data from the SUIS enables comparison across studies of a samples' propensity for and use of imagery in daily life which may inform future research questions.

Brief Core Schema Scale (BCSS, Fowler et al., 2006). The BCSS uses 24-items and a five-point rating scale, to assess beliefs about the self and others. Strong internal consistency has been reported across non-clinical and clinical samples (0.78 to 0.86; Fowler et al., 2006). The BCSS informed participants' formulations.

Working Alliance Inventory-Short Revised (WAI-SR; Hatcher & Gillaspy, 2006). The WAI-SR assesses the participant's and therapists views of the therapeutic relationship across 12 self-report items on a 5-point Likert scale. The client version displays good validity (r = 0.80) and excellent internal consistency (α = 0.92; Hatcher & Gillaspy, 2006), as does the therapist version (α = 0.94, r = 0.79; Hatcher et al., 2020). Within a sample of 64 participants with non-affective psychosis the WAI-SR demonstrated excellent reliability for clients (α =

0.91) and therapists (α = 0.85) respectively (Huggett et al., 2021). Scores from the WAI-SR enable the exploration of changes in the therapeutic relationship.

Two Weeks Post-Intervention:

Adverse Effects in Psychotherapy (AEP; Hutton, 2016). The AEP is a self-report measure asking participants to rate a range of potential adverse events in psychotherapy across a 5-point Likert scale on 28-items.

Administration of Measures

The majority of measures were input into Qualtrics, a secure online survey programme and completed by participants. Only the Psychotic Symptom Rating Scales PSYRATS, PANSS Positive subscale and CDSS were administered by AC as they are scored based on information acquired through clinical interviewing and semi-structured questions.

[TABLE 1 HERE]

Procedure and Intervention

Participants were recruited through an online advertisement (Appendix B) posted on Twitter, Facebook and via email to third sector services e.g. mental health charity 'Mind'. Following recruitment, participants were randomised to multiple baselines, (minimum of three, maximum of five) by an independent researcher at another institution using a secure web-based randomisation programme (Sealed Envelope). The original ethical approval was granted for a proposed randomisation of between two and five baselines. However, when planning the randomisation list and asking an independent colleague to generate the seed (pseudorandom number generator PRNG), the researchers made a decision to have the minimum number of baselines as three, to ensure a sufficient number of datapoints to establish if symptoms were increasing, decreasing or stable. Following completion of baseline assessments, participants attended six online-intervention sessions. The intervention was based on a collaborative formulation completed by the participant and researcher. An

example formulation is displayed in Figure 1. It is based on themes from all participants and is not any individual's experience to ensure anonymity (Figure 1, from Taylor, Bee, et al., 2019). As part of the formulation participants were asked to rate distress caused by images, this was then reviewed in the final session in order to answer research question six regarding whether the intervention reduced a general rating of distress caused by images. Two weeks after completion of the intervention sessions, participants completed an online questionnaire and received an end of therapy summary, personalised to each participant. The online questionnaire contained a free-text box for participants to provide feedback about the intervention in line with research question seven.

Safety planning for recruiting patients remotely in the UK

During first contact with participants, a risk assessment was completed. Information was gathered on environmental risks, risk to self and risk to others (Appendix C). A risk management plan was collaboratively agreed and contact details for a next of kin and general practitioner were obtained. The limits of confidentiality were discussed and participants consented to the researcher contacting the named persons should risk increase or change. A clear risk protocol (Appendix D) was developed between researchers and a supervisor was always available throughout data collection in case of a risk situation arising. On a sessional basis, plans for the rest of the day, protective factors and any heightened emotions were identified.

[FIGURE 1 HERE]

Data Analysis

Descriptive statistics for the above measures are reported and are useful to characterise the clinical level of participants experiences, in particular the PSYRATS, PANSS and CDSS. The SUIS, MIPQ and BCSS informed the formulation and intervention,

as well as providing helpful markers of potential change prior to and following the intervention sessions.

Research questions one to four regarding feasibility were evaluated through the number of participants recruited, sessions attended and number of dropouts; information is visually depicted in the results section. Data from the AEP (Hutton, 2016), was analysed to answer research question five regarding the presence of any serious adverse events or adverse effects. Scores from PSYRATS delusions, MIPQ and rating of distress is analysed to explore research question six; does the intervention reduce general rating of distress caused by images? Research suggests that autocorrelation would threaten the validity of parametric statistics (Shadish et al., 2013).

Clinically significant change was a >25% reduction in scores from baseline to final therapeutic session. A 50% change was considered 'much improved' (Durham et al., 2003). Percentage differences were calculated in Excel by subtracting each participant's initial baseline score from their last intervention score and dividing these numbers by initial baseline score. In line with advice regarding pilot studies, *p*-values are not reported (Lancaster et al., 2004). Finally, visual inspection of the data and Cohen's *d* was conducted. Cohen's *d* compares two groups by calculating the difference between two mean and expressing it as standard deviation units, $d = (\text{mean}_{pre} - \text{mean}_{post})/\text{SD}(\text{mean}_{pre} - \text{mean}_{post})$. Parker and Hagan-Burke (2007), suggest that measures of effect size support visual analysis by providing an objective measure of treatment effect and enables the possibility of inclusion in meta-analyses and comparisons across studies. All analyses were conducted in Microsoft Excel (Microsoft Corporation, 2018).

Results

Feasibility of Recruitment

Ten people contacted AC for further information on the study and five completed the case series. Figure 2 shows participant movement throughout the study. Three potential participants were not eligible due to, 1) not experiencing intrusive imagery at present, 2) being aged outside of inclusion criteria, 3) currently receiving treatment on a mental health inpatient ward. Two participants did not reply to the email containing the information sheet; therefore it is unknown if they were eligible for the study. Of the five who took part, two participants became aware of the study through their local Hearing Voices Group. Three participants saw the advert on social media, two on self-help forums on Facebook and one on Twitter. This demonstrates that it was possible to recruit participants to a telehealth case series.

[FIGURE 2 HERE]

All five participants attended the number of baselines to which they had been randomised and completed all six therapeutic sessions. Following feedback from one participant that fortnightly sessions would be more feasible and acceptable for them, an ethical amendment was submitted and agreed to increase the time in which the intervention was delivered. A reasonable level of attendance was set prior at three sessions by Taylor et al., (2020). All participants in the study exceeded this threshold. Participants one and three completed three baselines, participants two and five completed four baselines and participant four completed five baselines. All participants were retained in the study and attended all therapy sessions (100% attendance). Retention was strong and no participant withdrew from the study. This data answers some research questions, specifically, 1) that it is possible to recruit participants to a telehealth case series, 2) retention of participants is high (100% attendance rate), 3) completion of baselines and therapeutic sessions offered was high (all

five participants completed all sessions, 100% completion rate). It was not possible to answer the fourth research question regarding reason for participant drop out as there was no data available for this given the 100% completion rate.

Research question five exploring serious adverse events or adverse effects was answered through data collected from the AEP. No adverse effects were reported, although some items were scored as ‘very little’ and ‘a little’, for example, one participant responded, ‘a little’ to ‘taking part involved too much hard work’, the context for this was they were taking part in the research whilst beginning a new term at university. One participant responded, ‘quite a lot’ to the statement ‘taking part hasn’t helped me with my problems’. However, they also responded, ‘a little’ to the statement ‘my problems have improved to the point whereby I no longer feel I need help’. One participant responded ‘quite a lot’ in response to ‘I didn’t feel ready to talk about my problems’. All participants responded ‘not at all’ regarding statements about thoughts to harm themselves, negative effect on self-esteem, increase in anger and irritability and therapy taking up too much time. No serious adverse events were reported i.e. no self-harm, hospitalisations, suicidal ideation.

Demographic and Clinical Details

Five participants (all females) were recruited online, ages ranged from 22 to 57 years (mean = 41.2; *SD* = 13.20). All participants were under the care of National Health Service (NHS) Community Mental Health Teams in England. Participants self-reported diagnoses that had been made by a psychiatrist, two reported schizoaffective diagnoses (F25, ICD-10), one psychosis (F29, ICD-10) and two psychosis with delusions (F22, ICD-10). Two participants lived alone, three lived with family or partners. Two participants were separated/divorced, one was single, one was married and one was co-habiting with their partner. All five participants reported persecutory delusions and distressing images and met

inclusion criteria at assessment. Table 2 includes demographic information for each participant.

[TABLE 2 HERE]

Table 3 aids the visual inspection of the data and presents all measures used in the case series. Effect sizes are presented and reported throughout, however, should be considered within the context of a small sample size (*n*=5).

[TABLE 3 HERE]

Exploratory Measures

The PSYRATS delusions sub-scale and MIPQ are reported below with the aim to answer our research question regarding if the intervention reduced distress caused by images for the participants. This sixth research question is also answered by the distress rating participants reported during the formulation session of the intervention which was then reviewed in the final session.

PSYRATS Delusions

Visual inspection shows that all five participants experienced a reduction in delusional beliefs from first assessment to last intervention session. Figure 3 shows a declining trend in delusional beliefs for participants one to four over the course of the intervention. The graph for participant five indicates a downward trajectory during baseline and throughout intervention. Three participants reported improvements that met criteria for clinically significant change, (participant three, 45% reduction) with two of these three participants noted to be much improved (participant two, 50% reduction; participant four, 100% reduction). Scores for participants one and five also decreased by 13% and 24% respectively

but did not meet criteria for clinically significant change. Overall, a large effect size was found (d = 0.87).

[FIGURE 3 HERE]

Imagery

Visual inspection demonstrated a reduction in MIPQ scores across questions one to five for all participants, except participant four. Figure 4 displays participant scores. Scores for participants one and five demonstrated a more limited downward trend than other participants. A downward trajectory during baseline and intervention is seen for participant one, whilst participant two has a slight increase throughout baseline, before a downward trajectory during intervention. Participant two scores are stable during baseline, there is a sharp increase at the start of the intervention, before a steep decrease to below baseline scores, which is maintained over the remaining four intervention sessions. Participant three's MIPQ scores increased during baseline, an overall reduction is clear throughout the intervention, however, one sharp increase occurs at therapy session three. Scores on MIPQ for participant four increased sharply at the end of baseline, they remained higher than baseline but did reduce throughout the intervention. Regarding specific questions on the MIPQ; all participants reported a reduction in how compelling and real the image was perceived. Vividness of the image, as well as absorption and preoccupation with the image, decreased for all participants except participant one. An additional two items concluded the MIPQ but were not included in analysis. They explored the participant's understanding of the role imagery played in changing their mood and the extent to which they could find positive or helpful ways of using the image. Three of five participants reported improved understanding and three reported finding positive or helpful ways of using the image.

[FIGURE 4 HERE]

As part of imagery formulation, participants described the emotions elicited by their intrusive image and its impact on the here and now (Taylor, Bee, et al., 2019). Emotional responses consisted of fear, dread, sadness and worry. These feelings were powerful with participants rating emotions on average 8.6/10, with higher scores indicating stronger emotion. At the end of intervention sessions, distress caused by images reduced from an average of 8.6/10 to 5.5/10. Images were described by all participants as feeling "very real", however, as their sense of control over images increased throughout the intervention they commented on the 'realness' reducing. Participants also reported feeling positive emotions such as relief, pride in themselves, amusement and joy as they rescripted images and practised imagery manipulation. Participant two commented that the image was now, "something that is mine", rather than feeling controlled by it. Scores on the SUIS increased for four participants, again, this may be due to the increased use of safe place imagery as a coping strategy or practice of imagery manipulation tasks that participants anecdotally described as 'fun'. A tentative hypothesis may be that as participants practiced imagery tasks their day-to-day use of imagery increased, this needs further, rigorous testing.

PSYRATS Hallucinations

Alongside the PSYRATS delusions sub-scale, the PSYRATS hallucinations sub-scale was completed at every session. Participant five experienced clinically significant improvement, scores dropped from 33 to 24, equating to a 27% reduction in hallucinations. Participants three and four had reductions of 17% and 19% respectively. This was not clinically significant change. Participant two reported no hallucinations throughout baseline. They heard minimal whispering voices during the intervention but at the end of the intervention no hallucinations were reported. Participant two attributed the increase in voice-hearing during intervention to a change in care team and disruption in her routine which she

found stressful. They reported the voices were not distressing and understood them as a stress response and, “a cool thing the brain can do”. Once settled in her new routine she no longer heard whispers or voices. Participant one reported chronic voice-hearing in the context of complex trauma history and hallucinations scores remained somewhat stable and unchanged throughout

Visual inspection demonstrated an increase in auditory hallucinations during intervention for participants one and two, before a return to baseline scores at the last intervention session. A downward trajectory for participants three and four was evident which demonstrates a reduction in severity of auditory hallucinations. Participant five scores displayed an increase over baseline, followed by a decrease throughout intervention to below baseline scores. There was a small overall effect size (d=0.26) with three participants reporting a reduction.

PANSS Positive Subscale

The PANSS positive subscale provided a measure of participants’ experiences of positive psychotic symptoms. All participants reported a reduction in PANSS positive subscale scores, including participant one who experienced a 6% improvement in their positive psychotic symptoms. Two scores were clinically significant: participant three scores decreased from 16 to 12 resulting in a 25% improvement and participant four had a 40% improvement from 15 to 9 in pre- and post- intervention scores. A large effect size was found (d=1.46).

Schema Change

Average scores on the BCSS from initial assessment to end of therapy varied as depicted in Figure 5. Comparing average scores from pre- to post-intervention a reduction was noted on the negative-self subscale, suggesting improvement. However, positive-self scores also decreased. Positive-other increased suggesting improvement on this sub-scale,

but, negative-other also increased. Visual inspection demonstrated that negative-self decreased and positive-self decreased for participants two and three. Participant two negative-self improved by 67%, participant three improved by 100%, however positive-self scores decreased by 39% and 15% respectively. Similar dichotomies are seen in negative- and positive-other scores, which both increased for participants three and five.

Negative-self improved for participants two, three and five, by 67%, 100% and 18% respectively. However, positive-self also reduced due to the scores of two participants. Participant two's sense of positive-self reduced by 39%may have reduced due to changes in their family life that had left them feeling unsure of their role/identity. Participant three reported challenges at work and their positive-self score decreased by 15%. Their work stressors had worsened over the course of the intervention and they were facing barriers to accessing more therapeutic interventions. Two participants' scores were unchanged and participant four reported an improvement of 6%.

Positive-other improved for participants one, three, four and five by 100%, 25%, 70% and 75% respectively, with medium to large effect sizes, a 6% decrease was reported by participant two. Despite the improvement on positive-other, negative-other also increased. Scores for three participants were unchanged, however participants' three and five scores increased. Participant three increased score may be due to the difficulties at work and perceived lack of support they were experiencing there. Participant five faced similar difficulties but in the context of a return to studying at university.

[FIGURE 5 HERE]

Mood

Scores on the CDSS as a pre- and post-intervention measure decreased for four participants whilst pre- and post-scores for participant four remained at zero. The scores of

three participants were noted to be ‘much improved’. Participants two, three and five experienced increases of 50%, 67% and 58% respectively. There was a medium effect size. (d=0.69). Furthermore, all participants reported improvement in sessional mood rating with four experiencing clinically significant change, a large effect size was found (d=-1.44).

Summary and Qualitative Feedback

The final research question aimed to explore participant feedback on the intervention. These data were collected via Qualtrics, following completion of the AEP at two-week follow-up. Both versions of the WAI indicated improvements in therapist and client perception of the working alliance. Large effect sizes were found for both the WAI-therapist (d = -2.55) and WAI-client (d = -1.13) with increases for all five participants reported. Table 4 summarises participant changes and feedback.

[TABLE 4 HERE]

Discussion

The feasibility and acceptability of an imagery focused approach via telehealth were tested in a population of people who self-reported persecutory delusions and schizophrenia-spectrum diagnoses. Overall, results indicated that this approach is feasible and acceptable to be delivered via telehealth to this population. Each participant experienced clinically significant improvement on at least one measure. Furthermore, all participants reported a decrease in delusions according to the PSYRATS delusion sub-scale (Haddock et al., 1999).

Our first prediction was that it would be possible to recruit participants to a telehealth case series. Five eligible participants consented to take part and completed a risk assessment and safety plan. A flexible approach regarding appointments was employed, for example, one ethical amendment was submitted to increase the maximum length of time the case series could take in line with feedback from participants. A participant commented that this had felt

particularly person-centred, akin to research that found the flexibility of appointments to be helpful for people with psychosis (O'Toole et al., 2004).

Regarding completion and dropout rates, all five participants completed baseline and therapy sessions. There was also a 100% completion rate of all measures and no participants dropped out of the study. No serious adverse events were reported and a strong therapeutic relationship quickly supported participants to overcome some initial nerves about trying imagery focused techniques.

A reduction on the imagery measure, MIPQ, was found for four of five participants. Lower scores on the MIPQ suggested a reduction in imagery characteristics, such as vividness. Consequently, imagery distress also reduced, supporting the hypothesis that imagery can maintain and exacerbate mood states (Holmes & Mathews, 2010). This hypothesis was initially developed in samples of people with bipolar disorder and further research is required within psychosis more specifically. All self-report measures were completed by participants online, however, the interpretation of the MIPQ scores was negatively impacted as it was unclear what image the participant was rating when they completed the measure. MIPQ scores could also be understood in the context of some participants choosing to work on multiple intrusive images throughout the intervention. Variation may have been due to participants answering the MIPQ in relation to a different image than was the focus of the previous intervention session. For example, the increase in participant four's MIPQ and SUIS scores may be understood by their frequent use of safe place imagery. They reported practicing daily to create an immersive safe space that they found useful to visualise when feeling distressed.

Participant feedback on the intervention was gathered in clinical notes throughout and qualitatively two weeks post-intervention. Baselines and repeated measures were well tolerated with a stable baseline being established for all participants although this is not

always possible, particularly for people with psychosis due to the frequent fluctuations in symptoms (Bak et al., 2016). Given the briefness of the intervention, the use of multiple baselines, whilst strengthening the methodology, also provided an opportunity to gather information, allowing for swift progression to formulation. It is widely acknowledged that a formulation based approach allows for a shared understanding between the person experiencing the distress and the clinician (British Psychological Society, 2014; Division of Clinical Psychology, 2013), something found to be valuable for people with psychosis (Flach et al., 2015). Participants appeared to most highly value the connection between their previous experiences and intrusive imagery, as well as the emotional responses elicited. A result also reported by Morrison (2004).

Comparison to iMAPS

Both this study and Taylor et al., (2020) found similar reductions in participants' experiences of delusions, decreases in PANSS positive subscale scores indicating improvements of positive psychotic symptoms and improved therapeutic relationship as measured by the WAI-SR. Similar variability in MIPQ and PSYRATS delusions scores were also reported. Two main differences in outcome measures can be found between these case series. This study found improvements in mood, with large effect sizes found on both the CDSS and sessional mood Likert scale, Taylor et al., (2020) reported no improvement in mood. Given the difference in case series samples, how they were recruited and small sample sizes it is not possible to attribute this improvement in mood to the telehealth delivery. Secondly, improvements in schemas as demonstrated by the BCSS were found across all sub-scales by Taylor et al., (2020). However, we only found improvements for negative-self and positive-other subscales, with negative other increasing slightly and positive-self reducing slightly. Variation in BCSS scores have been reported within the Results section and as described scores may be sensitive to events external to therapy e.g. other relationships.

Changes may also be due to factors of internal validity or could be a negative signal, therefore future research may employ a more regular measure to check for potential negative effects. If a similar pattern to the present case series is observed in a more robustly collected and larger data set, it may be measuring a defensive reaction to increase in positive-other as suggested by Bentall et al. (1994).

Between case series the difference may be explained by the lack of explicit focus on schemas within this study. Taylor et al., (2020) used multiple measures of schema and schema features within the assessment and psychoeducation part of the approach, as well as within imagery rescripting sections. Regarding schema change, whilst Taylor et al., (2020) reported two participants with clinically significant change in schemas, other research suggests that schemas are stable and somewhat resistant to change, particularly within such brief interventions (Beck, 2020).

Experience of Telehealth

Recent research in the remote delivery of CBT for psychosis suggests that people may experience a sense of unreality in virtual encounters and worrying thoughts related to technology and surveillance (Kopelovich & Turkington, 2021). This was addressed in the initial assessment. One participant shared similar concerns as they described how interactions via telehealth could add to the distress caused by a delusional belief that they and the world were not real. Particularly difficult were audio delays, disrupted connections and videos freezing on screen. Time was spent considering how to minimise these potential issues and what techniques could be used for managing distress e.g. grounding techniques and alternatives such as telephone calls. The participant was able to complete all sessions via Zoom and these beliefs subsequently reduced as imagery associated with the person's beliefs became less threatening. Regarding surveillance thoughts, another participant reported persecutory delusions that she was being actively spied on by people meaning to cause her

harm. Initially, baselines were completed online via Zoom, however, this felt uncomfortable for the participant and remaining baselines and therapy sessions were completed by telephone instead.

The pandemic resulted in many barriers for the general population, particularly for those with mental health needs. For those with access to technology, stable internet access and mobile-based technologies, as well as a safe and private space in which they could engage, it appears an imagery-based intervention delivered through telehealth is acceptable and feasible. Participant feedback indicated that telehealth provided access without the fear of navigating new social environments and enabled them to engage more openly. By engaging from their homes participants reported feeling safer with the reassurance of soothing or grounding objects, pets and people nearby. One clear shortcoming of telehealth is the need for people to access private spaces in which they can fully participate. Three participants reported difficulties with this, leading to some sessions having to be re-arranged. This potentially strengthened the therapeutic relationship as participants reported that this flexibility had made the experience feel like a collaborative and shared approach (Byrne et al., 2010).

Limitations

The sample comprised of participants from a range of ethnicities and ages but a clear limitation was that all participants were female. Being female is a robust predictor of positive outcome in people with psychosis, even when considering symptom severity (Brabban et al., 2009). There were only female participants and as such, it is not possible to comment on or explore the therapeutic outcomes across genders.

Whilst the study design was suitable for the early stage of research in this area the methodological rigour could be improved in several ways. A control group would allow for improvements in symptoms to be more confidently attributed to the intervention.

Furthermore, due to resources, no independent assessor was available to complete baseline assessments and measures. The therapist (AC) completed all measures, baselines and intervention sessions with participants, which may have increased the likelihood of demand characteristics being present. This was managed to a degree by having some measures on Qualtrics, particularly the post-intervention two-week follow-up questionnaire which also asked for feedback on the case series. Finally, the lack of a follow-up assessment means it was unclear if participants maintained therapeutic benefits following the final intervention session. However, this is acceptable within a case series design.

Recruitment online was feasible and acceptable; although convenience sampling may have resulted in a bias towards people who had a higher level of functioning and results cannot be easily generalised. Another consideration is that people with higher conviction in their persecutory beliefs may have been less likely to participate. Furthermore, participants self-reported a diagnosis of psychosis, which we were unable to confirm with their care team or general practitioner.

The battery of measures used was reduced from iMAPS (Taylor et al., 2020) in an aim to manage potential fatigue which we hypothesised could be an issue online. However, anxiety disorders and trauma histories are commonly experienced in a sample such as the one included and were discussed by some participants, but they were not formally assessed or examined.

Future Research

This study replicated the findings of the iMAPS case series (Taylor et al., 2020), but in an all-female sample, across a range of cultures and in a telehealth setting for the first time. With a reduction in psychotic symptoms, improved mood and no serious adverse events, our results suggest that iMAPS via telehealth should be evaluated further. Given the limitation of an all-female sample, future studies should aim to recruit and explore the usefulness of this

intervention across other genders. Future research would benefit from control groups receiving treatment as usual to compare against an iMAPS intervention group. Extended follow-up length would provide the opportunity to explore if therapeutic gains are maintained.

Summary

This study recruited a sample of people with self-reported psychosis diagnoses and persecutory delusions from the general population. With similar clinical presentations as those recruited from NHS settings, the results have indicated that this type of recruitment is acceptable and feasible. It also offered the opportunity to try new and developing treatment interventions to people not under the care of NHS. Furthermore, the experiences of the participants involved in this research add to the growing body of literature that people with psychosis and persecutory delusions experience intrusive and distressing mental imagery. This imagery can be linked to psychotic symptoms such as voice-hearing and imagery-formulation can add a deeper understanding to that person's experiences. Additionally, it appears that existing imagery can be targeted to make it less distressing or safe place imagery developed to provide the person with feelings of safety.

Full attendance at sessions and no serious adverse events indicates the intervention is feasible and acceptable. Scores on delusions decreased for all participants, distress caused by images decreased for all and imagery characteristics decreased for four of five. Large effect sizes on PANSS positive subscale and mood scores are also promising. Furthermore, participants each reported clinically significant change on at least one measure. Therefore, imagery-focused techniques delivered remotely via telehealth should be evaluated further and address some of the limitations identified above, for example, the inclusion of a control group and blind assessor This intervention may be useful as a standalone treatment, or module within a longer piece of therapeutic work.

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Tables and Figures

Table 1

Details of measures to be completed and session content throughout the study

Session Title	Number of Sessions	Measures	Session Content
Initial Assessment	N=1	None	Gain informed consent, complete collaborative risk-assessment (Appendix C)
Baseline Sessions	Minimum 3, maximum 5	*First Baseline:* PANSS positive subscale[a], CDSS[a], SUIS, BCSS, WAI-SR *Remaining baselines:* PSYRATS[a], MIPQ, sessional mood	1. Participant completes measures; PANSS positive subscale and PSYRATS conducted in session through semi-structured interviewing by the first author a. Participant provides information on delusions, hallucinations b. Discuss other measures which can be completed on Qualtrics or with first author, including discussion of imagery
Telehealth iMAPS Intervention	N=6 Sessions 1-6	Session 1-5: PSYRATS[a], MIPQ, sessional mood	1. Assessment andgoal setting a. Introduce mental imagery and identify participants mental image b. Complete example of imagery diary and ask participant to complete between sessions c. Goal setting e.g. reduce distress associated with images, increase sense of control over image 2. Formulation, safe-place imagery a. Using information from assessment and diary develop formulation (see Figure 1 for example) b. Safe place imagery introduced and developed 3, 4 & 5: Introduce/practiceimagery techniques, examples provided below a. Participants introduced to imagery techniques based on formulation and goals. E.g. image of cult members spying on participant

Session Title	Number of Sessions	Measures	Session Content
			b. Imagery manipulation e.g. remove devices cult use to spy with c. Imagery rescripting: participant keeps feeling associated with image, removes image from mind's eye and explores spontaneously generated image. E.g. watched by teachers, participant described image content, introduced compassionate other to intervene and help situation, feeling of protection, hope and control d. Imagery-related behavioural experiments. Participant makes prediction about what consequence of bringing intrusive image to mind is and safety behaviours dropped, participant tests this within and between sessions. e. Image suppression,
		Session 6: PANSS positive subscale[a], CDSS, SUIS, BCSS, WAI-SR	6. Consolidate techniques and end therapy a. Review goals and imagery techniques participant found most useful and least useful b. If only one image worked on throughout discuss how to apply techniques to other images c. Agree what first author will include in 'end of therapy' summary
2 weeks post-intervention		AEP	Participant completes measure Participants receive personalised 'end of therapy' booklet outlining their formulation and techniques they had found most useful

[a] Semi-structured interview measures completed via telehealth with participants at the start of each session. All other measures completed by participants on Qualtrics.

Figure 1

Example imagery formulation.

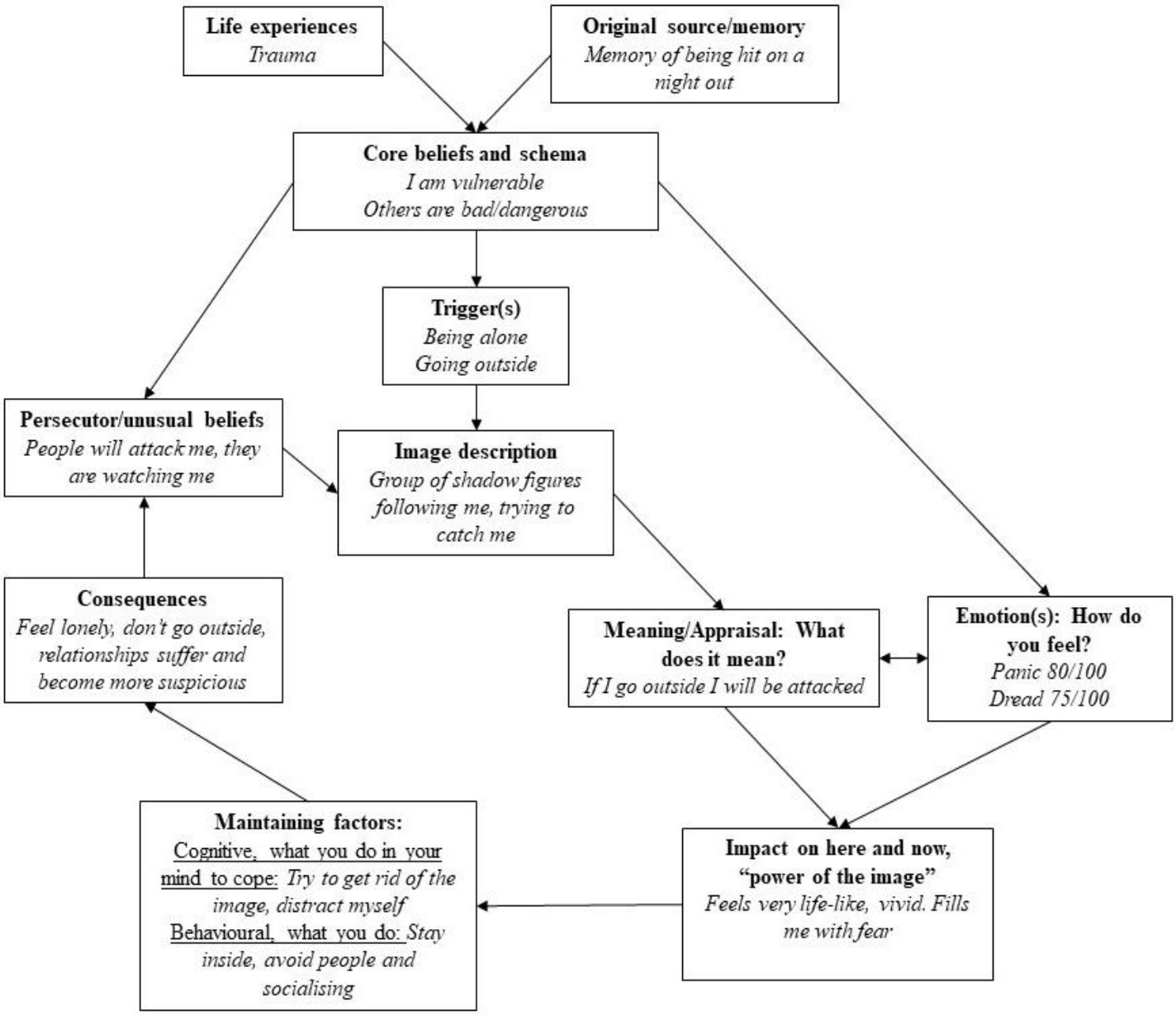


Figure 2

Flow diagram of recruitment and participation

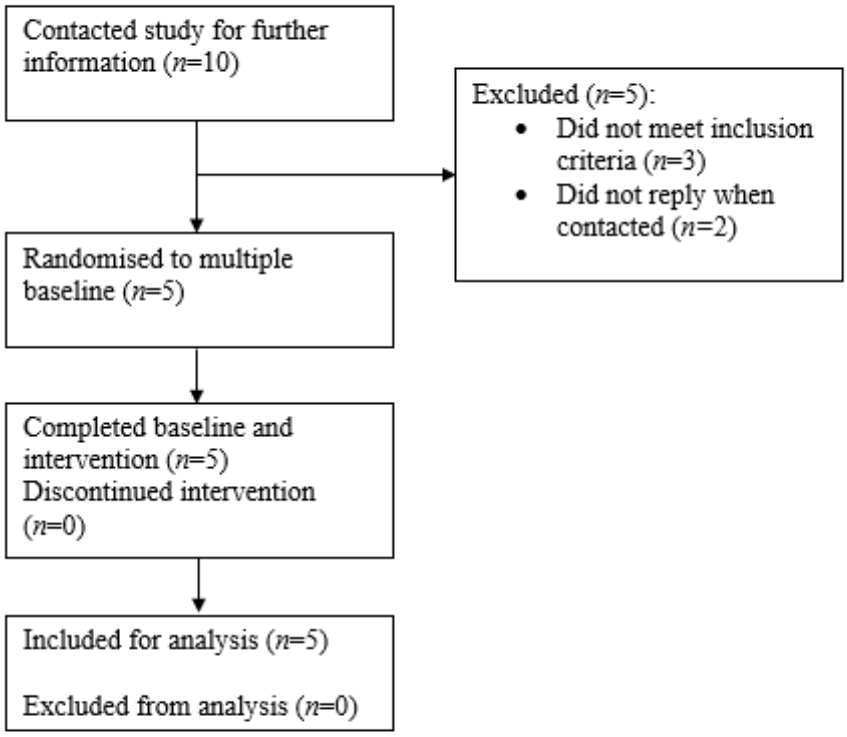


Table 2

Demographic information for all participants (n=5)

Participant Number	Age	Ethnicity	Self-reported Diagnosis	Education	Employment	Number of Baselines
1	57	White British	Psychosis with delusions	Further Education	Unemployed	3
2	41	British Asian Indian	Psychosis with delusions	Higher Education	Unemployed	4
3	49	White British	Psychosis	Higher Education	Part-time	3
4	37	Pakistani	Schizoaffective	Higher Education	Part-time	5
5	22	British Asian	Schizoaffective	Higher Education	Student	4

Table 3

Outcome data for all measures and Cohen's d effect sizes

Measures	First Baseline (*n*=5) Mean *(SD)*	End of Treatment (*n*=5) Mean *(SD)*	Cohen's *d*
	Pre and Post Measures		
PANSS Positive subscale	16.0 (1.58)	12.6 (2.88)	1.46
CDSS	5.4 (4.67)	2.8 (2.59)	0.69
SUIS	32 (10.42)	33.6 (7.16)	-0.18
BCSS – NS	7.8 (8.44)	6 (7.58)	0.22
BCSS – PS	12.8 (8.50)	10.8 (6.69)	0.26
BCSS – NO	5.8 (3.27)	6.4 (3.91)	-0.17
BCSS – PO	9.8 (5.67)	13.2 (4.49)	-0.66
WAI-SR: Therapist	31.8 (2.28)	41.6 (4.93)	-2.55
WAI-SR: Client	40.8 (7.50)	50.8 (9.96)	-1.13
	Sessional Measures		
PSYRATS Hallucinations	23.2 (13.81)	19.8 (12.44)	0.26
PSYRATS Delusions	12 (4.58)	7.6 (5.50)	0.87
MIPQ (Q1-5)	30 (11.18)	27 (9.51)	0.29
Mood (0-10)	4.8 (1.92)	7.2 (1.48)	-1.40

Figure 3

Changes to PSYRATS delusion scores across baselines and intervention sessions

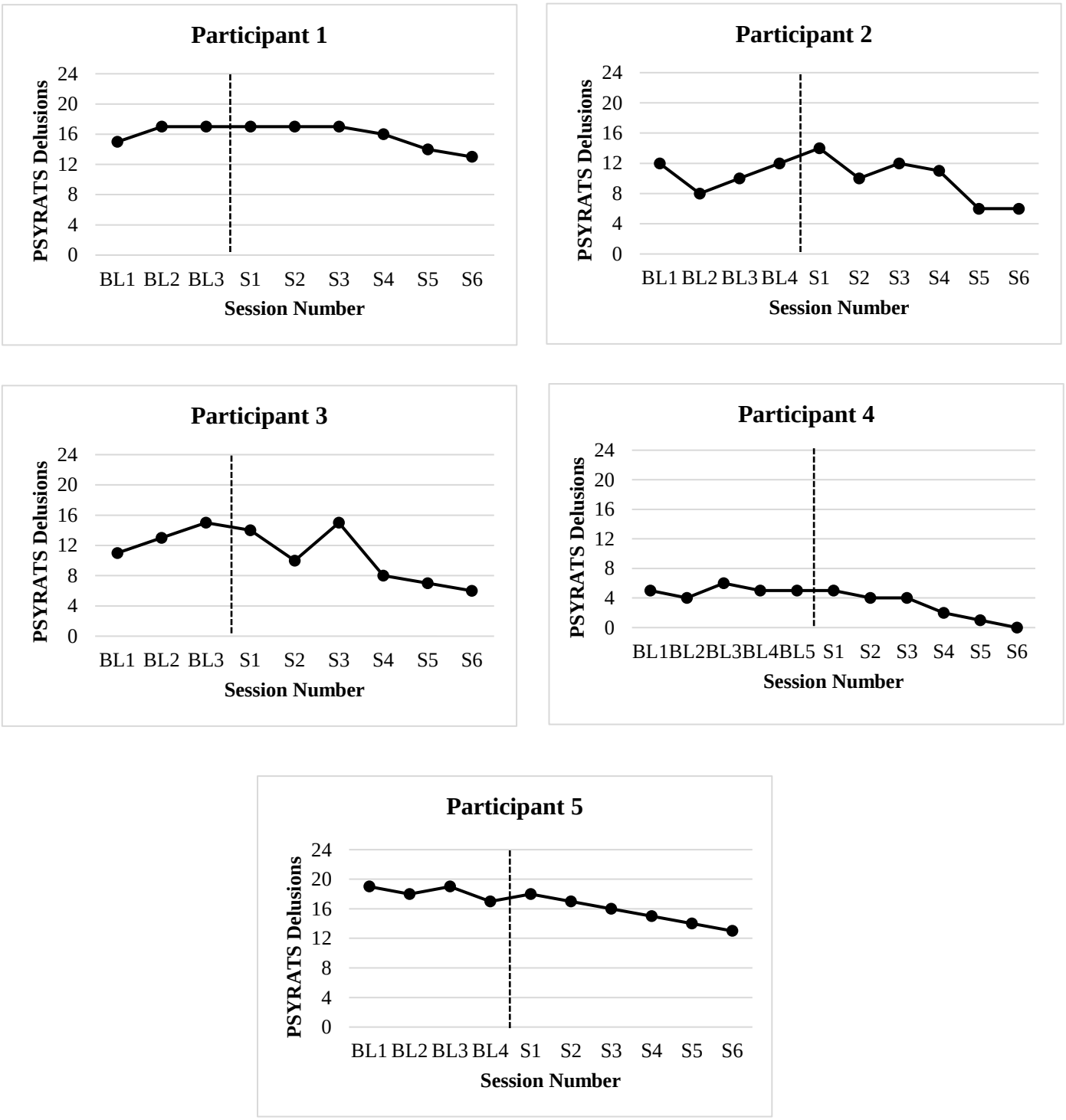


Figure 4

Changes to MIPQ scores across baselines and intervention sessions.

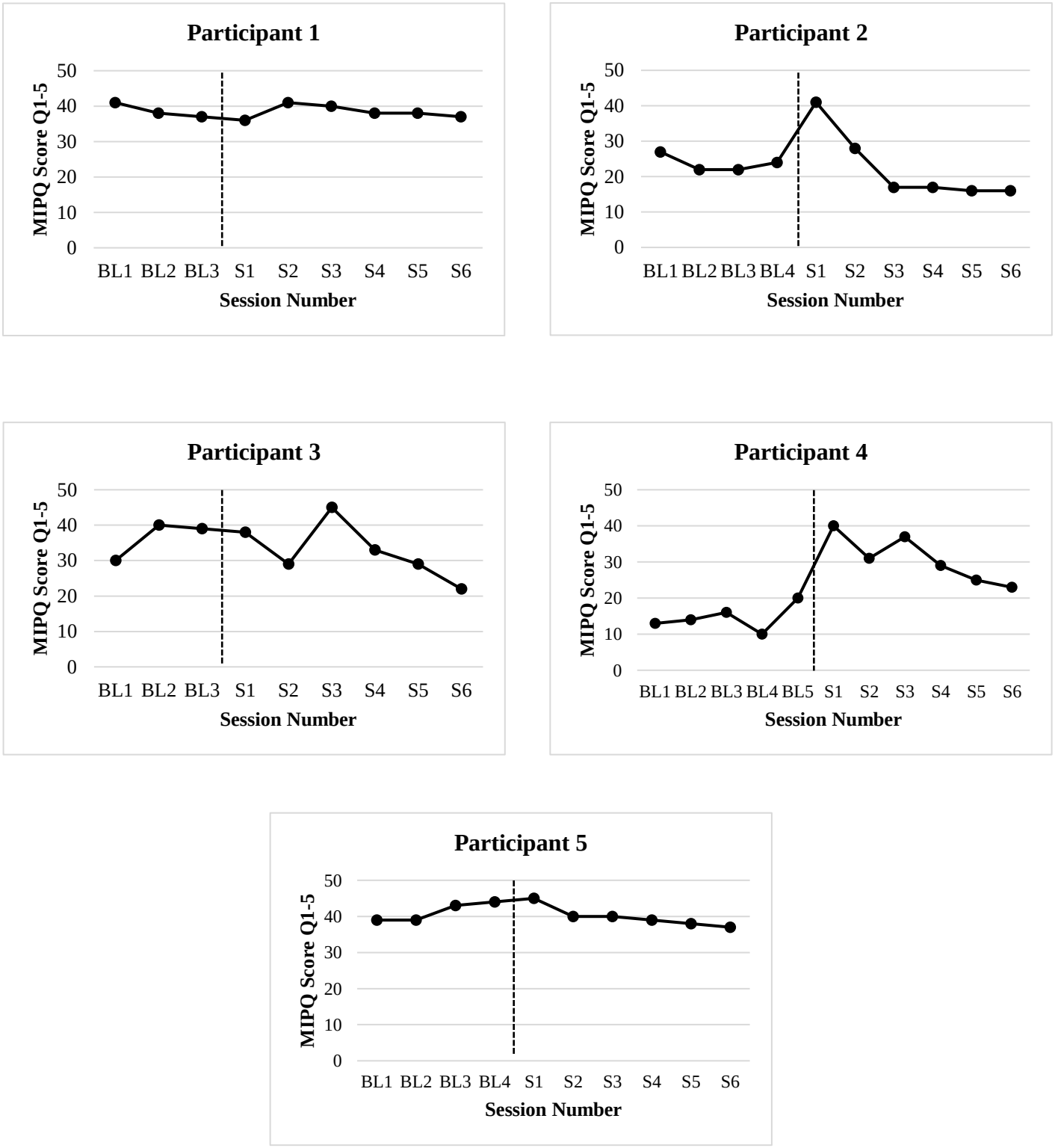
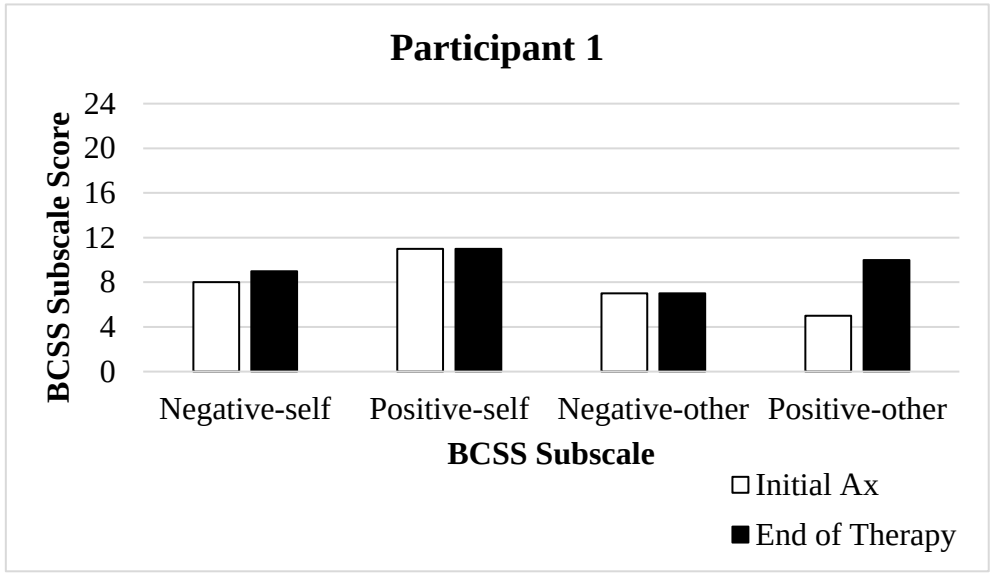
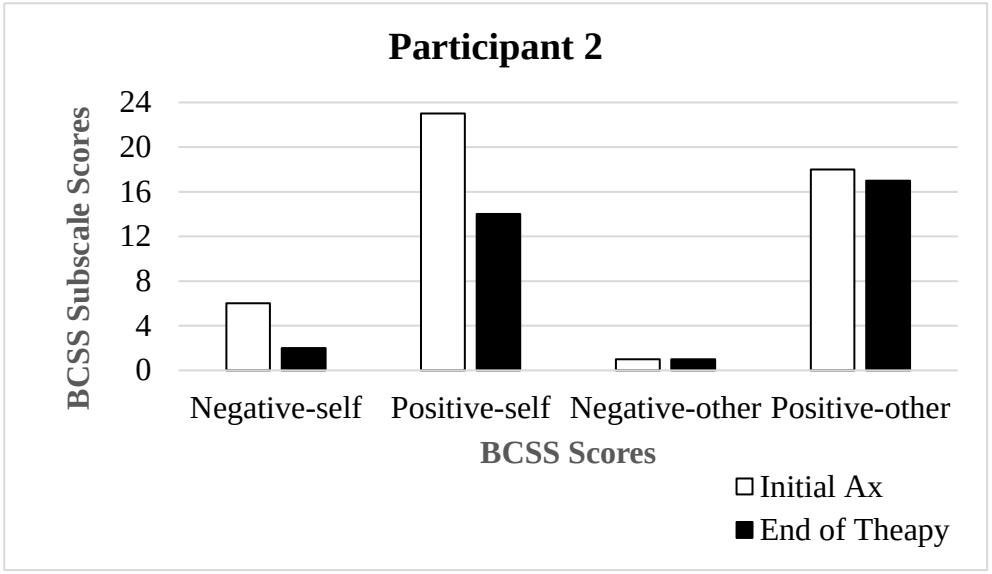
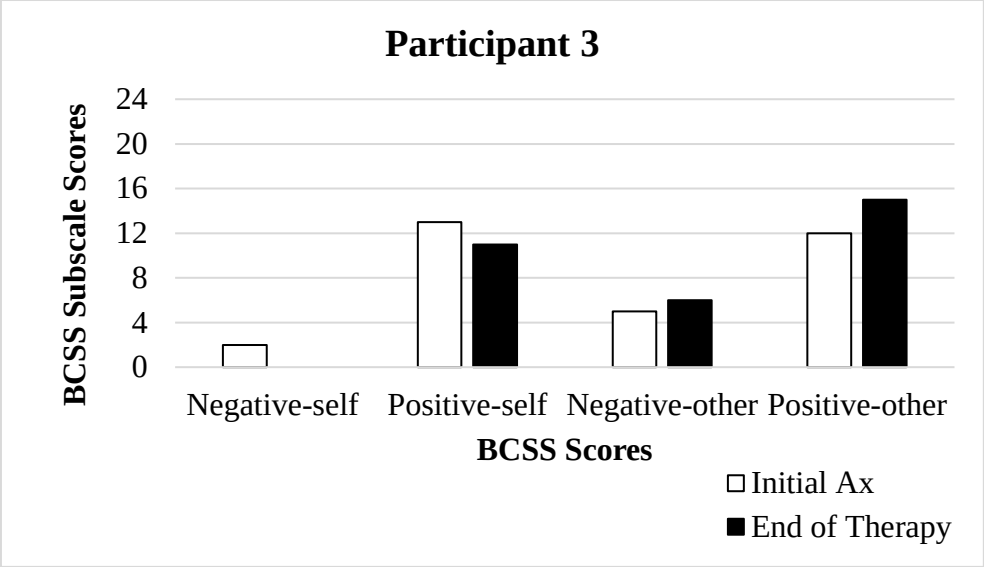


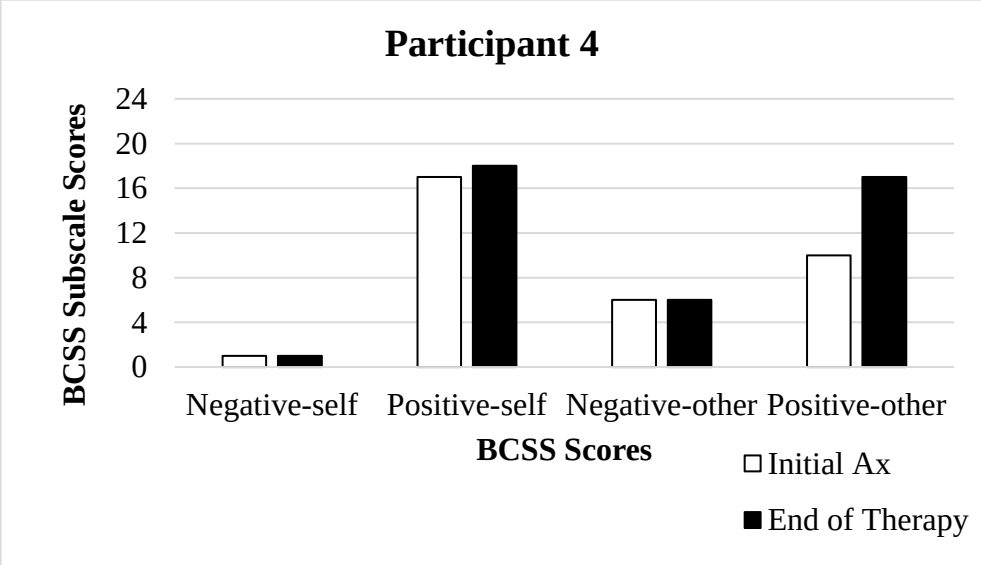
Figure 5

Changes to participant scores on the Brief Core Schema Scale.






Participant 3
BCSS Subscale Scores
24
20
16
12
8
4
0
Negative-self
Positive-self
Negative-other
Positive-other
BCSS Scores
Initial Ax
End of Therapy


Participant 4
BCSS Subscale Scores
24
20
16
12
8
4
0
Negative-self
Positive-self
Negative-other
Positive-other
BCSS Scores
Initial Ax
End of Therapy

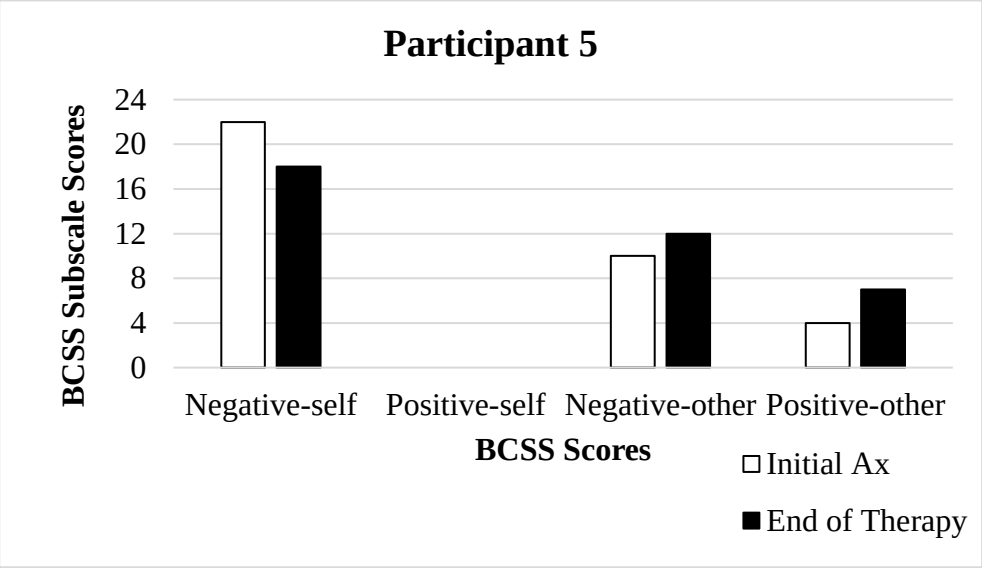

Participant 5
BCSS Subscale Scores
24
20
16
12
8
4
0
Negative-self
Positive-self
Negative-other
Positive-other
BCSS Scores
Initial Ax
End of Therapy

Table 4

Summary of changes and participant feedback

Participant Number	Summary of changes across measures.	Participant Feedback
1	Clinically significant improvement in sessional mood. Reduction in PANSS, CDSS, PSYRATS-Delusions, MIPQ. No change in PSYRATS hallucinations. Increase in SUIS.	"I really enjoyed a new way of working on my problems. I felt listened to and safe and have developed a new skillset".
2	Much improved in CDSS, PSYRATS-delusions and sessional mood. Clinically significant improvements in MIPQ and SUIS. PSYRATS hallucinations at zero throughout. Reduced PANSS	"It was really useful to learn new techniques and this was a type of intervention very different from anything I have ever done before…what I learned I can take away and develop on my own"
3	Much improved CDSS. Clinically significant improvement in PANSS, PSYRATS-delusions and MIPQ. Reduced PSYRATS hallucinations, improved sessional mood. Increase in SUIS.	"Useful and interesting to consider different ways of managing". Expressed an "increased sense of control" over intrusive images"
4	Much improved PSYRATS-delusions and sessional mood. Clinically significant improvement in PANSS. Reduced PSYATS hallucinations. Increase in MIPQ and SUIS. No change in CDSS, remained at zero.	"Summary was very helpful and a timely reminder that I can cope very well"
5	Much improved CDSS and sessional mood. Clinically significant improvement in PSYRATS hallucinations. Reduced PSYRATS delusions, PANSS and MIPQ.	"It was interesting looking at things with a different technique"

Appendices

Appendix A: Ethical Approval

Applicant: Aimee McMullan
Supervisor: James Kelley, Christopher Taylor
Department: DHR
FHMREC Reference: FHMREC20178 (Amendment to FHMREC20025)

15 July 2021

Re: FHMREC20178

Exploring the Feasibility and Acceptability of Online Imagery Focused Techniques for People with Psychosis

Dear Aimee,

Thank you for submitting your research ethics application for the above project for review by the **Faculty of Health and Medicine Research Ethics Committee (FHMREC)**. The application was recommended for approval by FHMREC, and on behalf of the Chair of the Committee, I can confirm that approval has been granted for this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer at the email address below (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information. Email:

fhmresearchsupport@lancaster.ac.uk

Yours sincerely,

[redacted]

Tom Morley,
Research Ethics Officer, Secretary to FHMREC.

Appendix B: Online Advertisement

Exploring the Feasibility and Acceptability of Online Imagery Focused Techniques for People with Psychosis

We would like to investigate anonline interventionfor people with psychosis in the community, who experience mental images and suspicious thoughts and beliefs.

Who can participate?

Do you become distressed by paranoid beliefs or do you wish to seek help for paranoia or suspicious beliefs?

Do you currently experience suspicious thoughts and beliefs?

Can you identify an image that comes to your mind that causes you distress?

Have you ever been diagnosed with Psychosis, Schizophrenia or Schizoaffective Disorder?

Are you between 18 and 65 years old?

Do you have reliable access to internet connection and a device that supports video conferencing e.g. Teams or Zoom?

Do you have access to a safe and confidential space for therapy sessions?

What would you be asked to do?

- Initial assessment session = 1 hour
- Baseline sessions (min 2, max 5) = 10 -30mins each
- 6 online -therapy intervention sessions = 1 hour
- Questionnaires before, after and during therapy to see if you found the online format feasible and acceptable.

All sessions will be over Teams or Zoom with a trainee clinical psychologist. Intervention sessions will use a range of imagery techniques

If you are interested, please contact:

Aimee McMullan (a.mcmullan@Lancaster.ac.uk)

Lancaster University

Appendix C: Risk Assessment

Eligibility Screen	
Potential Participant ID:	
Name of person completing form:	**Date of form completion:**
Inclusion criteria details: Aged 18-65? Y/N Diagnosis of psychosis, schizophrenia-spectrum disorder, schizoaffective disorder? Y/N Experience persecutory delusions, paranoid beliefs or suspicious beliefs? Y/N	
Exclusion criteria details; Developmental disability (including autistic spectrum disorder)? Y/N Non-English speaking? Y/N Poses unmanageable risk of violence to researcher or clinician? Y/N **To be eligible, P must have N circled for all the above. <u>Remember,</u> further eligibility testing will also be required. Risk of harm to self or others must be assessed using the pre-visit risk assessment form overleaf.**	

Pre-Visit Risk Assessment

Potential Participant ('P') ID number:

Name of person completing form:	**Date of form completion:**
Nature of current contact with services: Inpatient ☐ Outpatient ☐ Other ☐ Specify:	**Previous contact with services (please specify):** _____ _____ _____

ENVIRONMENTAL RISK

Any environmental risk? Current □ Past □ Both □ None identified □

If current or past, provide details:

_____

_____

Risks with relatives/others? Yes □ No □ Don't know □ Not applicable □

If Yes, provide details:

_____

_____

Risks from animals? Yes □ No □ Don't know □ Not applicable □

If Yes, provide details:

_____

RISK OF SUICIDE OR SELF-HARM

Any risk of self-harm? Current □ Past □ Both □ None identified □

If Current or Past, provide details:

_____

_____

_____

If P has had previous suicide attempts, please specify number of attempts if known, method, locality, extent of concealment, level of intent, preparation

_____

_____

_____

_____

If P has current suicidal ideation, please specify frequency, duration, level of intent, access to preferred means of suicide:

_____

_____

_____

_____

Any recent stressors for P (illness, break-up, bereavement)? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Does P have fears of mental disintegration Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Has P recently been discharged from inpatient psychiatric care? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Does P engage in current alcohol and/or drug misuse? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Level of risk of suicide as judged by referrer: Low □ Moderate □ High □ Very High □

Referrer's rationale for rating:

_____

_____

_____

_____

_____

RISK OF HARM TO OTHERS

Any known risk of harm to others? Current □ Past □ Both □ None identified □

If Current or Past, provide details:

_____

_____

_____

Any risk of harm to children? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any risk of harm of sexual assault? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any incidents involving police Yes □ No □ Don't know □

If Yes, provide details (number, nature of incidents):

_____

_____

Any threats / thoughts / hallucinations / delusions

which indicate potential harm to others? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any previous convictions for violent crime Yes □ No □ Don't know □

If Yes, provide details (including whether planned or impulsive and whether weapons involved):

_____

_____

Diagnosis of antisocial personality disorder and/or presence of psychopathic personality traits?

Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

After consulting with P, describe P's risk management plan below:

(i.e., Is there a crisis management plan for P?; Who are the contacts in a crisis? Identify friend, family, caregiver, crisis teams who could be made aware of P's participation in the study. If there are any safeguarding issues disclosed by P during the study, what is the action plan?)

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

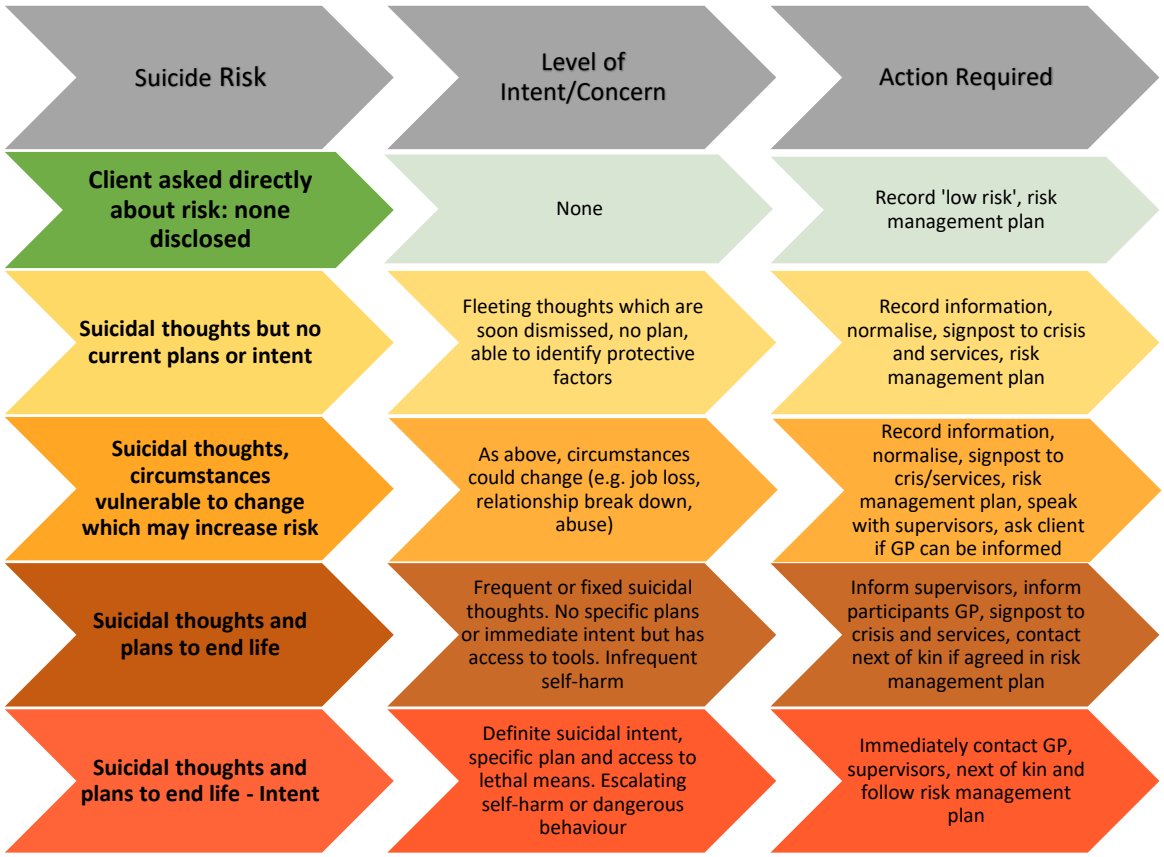
Do CI and RA agree that risk is manageable within the bounds of the study protocol?

Y/N

If N, then P is not eligible to participate.

Appendix D: Risk Protocol

iMAPS Online: Risk Protocol for Suicide Risk



Organisation	Contact details	Opening times
Samaritans	08457909090 or 116123	24/7
Sane	0845 767 8000 or sane.org.uk/textcare	18:00-23:00 daily
CALM	0800585858	17:00–00:00 daily
Greater Manchester MHFT NHS (Bolton, Trafford, Salford)	08009530285	24/7
North West Boroughs NHS	Wigan: 08000513253 Halton, Knowsley, St Helen's, Warrington: 08000511508	24/7

Section Three: Critical Appraisal

Word count (excluding references): 3,929

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The aims of this thesis were twofold; 1) consider the outcomes of imagery focused interventions for people with psychosis and delusions in a literature review; 2) explore if telehealth delivery of an imagery-based intervention was acceptable and feasible for people with persecutory delusions using a multiple baseline case series.

This critical appraisal summarises the main findings, strengths and limitations of the literature review and empirical paper. Key decisions, challenges and how these may inform future research directions are discussed. Furthermore, this thesis was completed within the context of Coronavirus-19 (COVID-19, SARS-CoV-2, World Health Organisation [WHO], 2022), the impact of which is considered at points throughout this section.

Main Findings

Systematic Literature Review

The literature review aimed to review the available evidence for the outcomes of imagery-focused interventions in people with psychosis and delusions. Eight papers were included. Seven studies reported decreases in measures of paranoia for people with psychosis and delusions following an imagery focused intervention. One study (Ascone et al., 2017) found no specific intervention effects for compassion focused intervention, however a decrease in paranoia was reported irrespective of group allocation. A range of methodologies were included e.g. case series, pilot randomised control trial and uncontrolled feasibility study. Overall, where data was available, studies appeared to be acceptable and feasible, with no serious adverse events reported.

Empirical Paper

The empirical study aimed to investigate the feasibility and acceptability of an imagery-focused approach via telehealth for individuals who self-reported persecutory delusions and experienced intrusive images. Each of the five participants completed all baseline assessments and six intervention sessions. No dropouts or serious adverse events

were reported. Participants experienced clinically significant change in at least one measure. All participants reported a reduction in the realness and compelling nature of distressing imagery.

Strengths and Limitations

Systematic Literature Review

This review is the first we are aware of to investigate mental imagery and delusions. Results indicated that whilst the papers included had small sample sizes and other methodological limitations, people with a range of schizophrenia-spectrum diagnoses could engage with imagery focused interventions. A further strength of this review was the use of a critical appraisal tool, Crowe Critical Appraisal Tool (CCAT v1.4; Crowe et al., 2011). The CCAT assesses for risk of bias across eight categories with a good degree of construct validity (Crowe & Sheppard, 2011). Research suggests many review proposals state the use of one tool for risk of bias assessment, however, these are often misapplied e.g. using a tool designed to assess risk of bias in a randomised controlled trial (RCT) to non-randomised studies; or tools unvalidated for use outside of RCTs (Farrah et al., 2019). Given the heterogeneity of designs presented within the review presented in section one, it was agreed that a tool designed and tested across a range of research designs (Crowe & Sheppard, 2011) was most suitable. It is worth noting that there is a general lack of consistent and appropriate risk of bias tools for use in non-randomised studies, with research inviting the development of more acceptable tools (Seehra et al., 2016; Waddington et al., 2017).

A systematic review was agreed to be the most appropriate approach by the research team, as opposed to a narrative review or meta-analysis. Unlike narrative reviews, systematic reviews have clear objectives, predefined eligibility criteria and a reproducible methodology (Jahan et al., 2016; Siddaway et al., 2019). A meta-analysis was not possible given the

heterogeneity of the studies regarding sample characteristics and psychometric measures used.

A main methodological limitation of the review was the absence of another researcher to review articles. This resulted in most papers being included or excluded based on the first author's assessment. If there was ambiguity regarding a papers inclusion the entire research team discussed it however, this is less methodologically rigorous. Only 25% of papers were assessed for quality by two people, again reducing rigor. Nevertheless this was more rigorous than a single reviewer evaluating all papers.

Empirical Paper

In the empirical study, a nonconcurrent A-B multiple baseline design was utilised with participants independently randomised to differing baseline lengths. A multiple baseline case study design was chosen and implemented over other methodologies, such as a RCT for several reasons. Firstly, Skivington et al., (2021) suggest conducting a case series as an initial stage in the development of complex interventions, making it the most relevant method for the empirical research presented in section two. Secondly, the use of multiple baselines allows for increased confidence that therapeutic improvement is attributable to the intervention, rather than to chance or the participant spontaneously recovering (Kazdin, 2019). Thirdly, sessional and pre- and post-intervention measures allow for the observation of change throughout baseline and as the intervention progresses. An RCT design on the other hand limits the use of measures typically to pre- and post- intervention (Krasny-Pacini & Evans, 2018). Finally, the design was well suited to practical considerations such as the demand of real-life clinical settings.

Findings from the case study indicated that recruitment of clinical populations without service involvement was possible online. Furthermore, participants completed sessional measures, both online self-report measures and semi-structured interview measures. This is

consistent with Johns et al., (2019) who reported the feasibility of using sessional measures with people with psychosis. The online nature of our case series appeared to be tolerable and ensured that sessions could continue regardless of national or local lockdowns. Furthermore, it allowed people with reduced access to services due to their geographical location to engage. It also enabled people juggling many demands to access the intervention by removing the necessity to travel for sessions. Participants reported that they could fit sessions into their daily routines more easily.

A clear limitation is that the sample only consisted of people self-identifying as female and lacked participants from other genders, it is important to consider why this may have been. Two males did enquire about the study but did not reply to follow-up emails. The study was also limited by the lack of follow-up measures, as such it was not possible to report if therapeutic improvements were maintained following the intervention. Lack of a blinded assessor is also important to note. A retrospective study of 63 RCTs investigating psychological interventions found that the blinding of key people e.g., therapists delivering interventions and assessors, was rarely documented or considered in published research (Juul et al., 2021). Juul et al., (2021) suggest that this might result in the benefits of the intervention being overestimated and the harmful effects underestimated. Finally, results have limited generalisability due to the small sample size. Research acknowledges that small sample sizes are important as they often focus on vulnerable populations (Etz & Arroyo, 2015), however, they can undermine the internal validity of research (Faber & Fonseca, 2014).

Key Learning Points and Considerations

The study was developed within the context of the COVID-19 pandemic. Within this context projects requiring ethical approval from the National Health Service (NHS) were advised against by the doctoral programme for several reasons; 1) to avoid the delay in

decisions regarding ethics proposals; 2) to attempt to ensure trainees on the programme would have a viable project for submission; 3) to lessen burden on the NHS; 4) support the prioritisation of projects directly related to COVID-19.

Therefore, a telehealth case series was conceptualised and ethical approval was obtained from Lancaster University (FHMREC) allowing the recruitment of people with psychosis and persecutory delusions from the general population. In hindsight, the project is relevant to considering the delivery of psychological therapies in pandemics. Telehealth studies and therapy predate the pandemic and wider potential implications exist, for example, rural and island-based communities that have used telehealth for some time to access healthcare assessment and interventions.

Recruiting Online

There has been a steady decline in research participation over the past thirty years (Caplan & Friesen, 2017). Challenges of recruitment in mental health are widely reported (Howard et al., 2009; Woodall et al., 2010). Research carried out through primary or secondary care face-to-face has several reported barriers impeding recruitment. For example, a review of 49 articles reported that participants widely cited transportation difficulties, suspicion of researchers and stigma as common barriers (Woodall et al., 2010). Recruitment in mental health services may also be hampered by clinicians who 'gatekeep' access to participants. Clinicians may perceive potential participants as 'too vulnerable' and seek to protect them from research. They may hold certain attitudes about research or an intervention and deem it futile. This could result in a filtering of participants, potentially leading to a sample that is no longer representative of the target population (Borschmann et al., 2014; Howard et al., 2009; Patterson et al., 2010). These barriers were anecdotally described by participants who took part in the case series outlined in chapter two. Participants three and four described being offered face-to-face therapy but feeling unable to engage due to: 1)

feeling too anxious to travel on public transport to access therapy; 2) feeling uncomfortable meeting strangers; 3) worries linked to persecutory delusions; 4) facemasks heightening distressing visual hallucinations. Therefore, by recruiting online and delivering the intervention via telehealth it is possible that some barriers associated with recruitment through existing mental health services and accessing a psychological intervention were overcome.

This thesis aimed to make online recruitment and a telehealth intervention accessible. However, it is important to explore who may have been inadvertently excluded. A systematic review was conducted that aimed to characterise the use and efficacy of social media in recruiting participants for mental health research (Sanchez et al., 2020). The review included 176 studies and found that whilst recruitment on social media was as good as, or better than, traditional recruitment methods, representativeness of samples recruited through social media had some imbalances. Gender and age were commonly imbalanced, as well as education with higher education typically overrepresented (Thornton et al., 2016). Whilst the review focused on studies that used Facebook to recruit to psychosocial, health or medical research, Thornton et al., (2016) found that mental health studies recruited higher proportions of females than physical health or substance use studies. These findings may help explain the empirical paper sample, who were all female and had all completed higher education. One participant completed further education and two were studying further education courses during the intervention. Regarding gender and age, research in Australia found that samples recruited from Facebook tended to overrepresent participants who were younger in age and female (Batterham, 2014). In our case series only two males contacted the main researcher (AC) for further information. Whilst there is a clear need to be tentative given the small sample included in the empirical, a hypothesis may be that the high levels of education and all female sample may be due to the online recruitment strategy.

Recruitment for the empirical study focused on social media groups specifically for people with psychosis. However, considering the stigma and barriers to help seeking for males as described by Ellis et al., (2013), advertising across a broader range of groups may have increased the likelihood of male participants becoming aware of the research. In the literature review in section one, male participants accounted for over half of the total sample; however, these studies were all conducted in the community and mainly within services, indicating that these male participants had already overcome some barriers to access support.

Unlike gender, age and ethnicity did not appear to have been negatively impacted. A broader age range and a more ethnically diverse sample was recruited for the telehealth case series, compared to Taylor et al., (2020), where a sample identifying solely as White British was recruited from an Early Intervention in Psychosis service. The sample included in this thesis are more representative of people with psychosis as research has found higher prevalence rates in Black African, Black Caribbean, South Asian, White Other and Mixed Ethnicity people in England (Halvorsrud et al., 2019).

Important to consider are the people who are unable to access therapeutic research or services irrespective of recruitment technique, i.e., online or in-person via existing services. There are several well documented barriers to treatment for people with severe mental illnesses like psychosis. One consideration is the individual's insight into their need for treatment, reduced insight has been linked with a refusal to seek treatment (Kumar, 2020). Problems with perception, cognition, motivation and interpersonal functioning have been noted to negatively impact people with severe mental illnesses. Stigma was heavily documented as a clear barrier to care for people across the lifespan, across occupations and across ethnicities (Corrigan, 2004; Corrigan et al., 2014). Whilst these barriers can be 'placed' within the person with psychosis and lead to additional stigma, other barriers exist at a service level. For example, when people with psychosis tried to access services, one study

found that the overall mean of duration of untreated psychosis was 260 days within the United Kingdom (Birchwood et al., 2013). Brief interventions such as that presented in the empirical paper may be beneficial for people waiting to access further treatment, however, there is also a need for the continued development of a range of interventions that vary in length, intensity and mode of delivery to meet the needs of this group.

Delivering an intervention via telehealth

A dominant theme throughout research in telehealth is the concern around a 'digital divide'. In both American and UK samples, research suggests that people with mental health needs are at a heightened risk of being excluded by the 'digital divide' (Dobransky & Hargittai, 2016; Tobitt & Percival, 2019). The 'digital divide' relates to barriers to digital means of therapy which include; lack of knowledge regarding technology, inadequate internet speed or no video-enabled device and lack of access to a private space (Firth et al., 2016). Whilst approximately 82% of the adult population in the UK own smartphones (Ofcom, 2020), there are concerns that the adoption of telehealth may exclude some demographic groups (Watson et al., 2021). Within psychosis populations more specifically, older participants and Black and Asian people were at increased risk of digital exclusion (Ennis et al., 2012). Robotham et al., (2016) replicated Ennis et al (2012) study five years later and whilst rates of exclusion were lower, approximately 18.3% of participants remained digitally excluded.

The case series reported in section two successfully recruited a sample from a broad age range and diverse ethnicity. Whilst all five participants had access to adequate internet, video-devices and ability to use equipment, two participants struggled at times to access private space. This required a level of flexibility with two intervention sessions being rescheduled. Flexibility such as offering a range of times and rescheduling appointments that are no longer suitable for the participant could enhance the feasibility of delivering effective

telehealth. However, with increasing pressure on services and a focus on the cost of missed or cancelled appointments, it is possible that a move to delivering interventions via telehealth without the flexibility suggested above could exacerbate the digital divide and leave people 'behind' due to digital exclusion.

Lastly, clinicians describe concerns that core symptoms of psychosis such as suspiciousness and paranoia may interfere with the acceptability of telehealth however, this was unfounded in two literature reviews (Santesteban-Echarri et al., 2020; Sharp et al., 2011). Research suggests that the client's primary concerns regarding telehealth are about connection issues such as poor audio quality or disrupted video display. In order for telehealth to be effectively implemented, time and resources need to be spent assisting clients to set up telehealth software and pre-emptively problem-solving connection difficulties (Paulik et al., 2021). Participants from the empirical chapter reported that discussing potential difficulties and planning for lost or interrupted connection was helpful and facilitated engagement.

Use of measures

It was agreed by the research team that self-report measures could be completed online or via telehealth with participants. All five participants opted to complete the measures online via an online survey hosting website. An advantage was participants could complete measures outside of the session and complete them more quickly, thus reducing screen time. However, a key consideration is that most self-report measures had only been validated for use as pen and pencil measures and not online completion. A systematic review of self-report scales used in telehealth psychotherapy found that the majority of measures had strong correlation between online and paper formats (Alfonsson et al., 2014). This finding was supported by van Ballegooijen et al., (2016) in a systematic review of the psychometric properties of online instruments that measure common mental health disorders e.g.

depression and social phobia. Research into the equivalence of online versus in-person scores for psychosis and imagery measures is lacking and is a potential area for future research. Finally, self-report measures can be useful tools to facilitate conversations between clinicians and participants. For example, the Mental Imagery in Psychosis Questionnaire (Taylor et al., 2019) has two additional questions that explore the impact of imagery on mood and imagery usefulness. Discussion of these questions and others, could enhance the understanding of the intervention, its usefulness and the participant's experience.

Risk Management

As previously stated, it was decided to recruit participants outside of NHS settings. Whilst the intervention was not expected to cause participants any distress, risk management and safety plans were designed and correlated with those used in NHS services. A risk assessment was completed with each participant in the initial meeting. Risk was assessed across three domains; environmental risk, risk to self and risk of harm to others. The assessment concluded with the development of a clear risk management and safety plan agreed collaboratively with the participant. As part of this assessment, participants provided contact details for their general practitioner, community mental health team and/or partner. Participants also consented to the researcher (AC) contacting those involved in their care if the participant experienced a decline in their mental health or a risk situation arose.

Thankfully no participant experienced a serious adverse event, however, a risk protocol for suicide risk was developed by the researchers to augment the risk assessment and safety plan. The information contained across these three areas meant that clear plans were in place to manage risk and clear actions for the researcher to take if risk presented. Furthermore, weekly clinical supervision was provided by research supervisors, (both experienced clinicians), with at least one supervisor available to be contacted ad hoc in case of risk or safeguarding concerns. The systematic procedures and scaffolded support meant

conducting research outside of an NHS setting still felt safe for the researcher AC and anecdotally for the five participants.

Future Research

Service User Involvement

In 2017 the Department of Health published a 10-year framework for mental health research, a key recommendation of which was patient and public involvement (PPI) in research. The case series by Taylor et al., (2020), the basis of our empirical study, was informed by service user consultation. However, service user involvement was not possible for the telehealth case series presented in section two. The pandemic negatively affected the feasibility of service user involvement as it reduced the amount of time available to design, recruit and complete the case series. Research highlights the benefits of service user involvement, for example, improved recruitment rates, more relevant outcome measures, and benefits for those involved in the consultation (Staley & INVOLVE, 2009). Qualitative research included the experiences of 38 people with lived experience who were involved in research (Crocker et al., 2017). Participants described how they helped form initial research questions and ideas and validated existing ideas. They also provided suggestions about how information was communicated to the target population.

Garety et al., (2021) described similar impacts of PPI in the more specific context of trials for psychosis. Communication was improved through the development of new recruitment meetings and PPI members attended meetings where service users from the target population were in attendance. PPI members reported their confidence, insight and career aspirations had been positively impacted and found the work rewarding and empowering.

Future research should involve PPI members throughout the design, data collection, analysis and dissemination of research. This could be facilitated through the development of a comprehensive and detailed plan informed by INVOLVE guidance. PPI involvement has

been described as a form of experiential learning for researchers, with the caveat that researchers ‘don’t know what they don’t know’, until people with lived experience are meaningfully involved in research (Staley, 2015). Furthermore, Garety et al., (2021) reported that people involved in PPI were in favour of assessing the impact of PPI in the hope that this would improve how it is conducted, reduce tokenism and convince more sceptical researchers of its value. However, they also acknowledged the difficulty of evaluating the impact of PPI involvement on research. Quantitative and qualitative evaluations may prove useful, as well as documenting and reporting tangible impacts throughout the research. A two-round Delphi study found consensus that, despite complexities, it is feasible to evaluate the impact of PPI on some research processes (Barber et al., 2012).

Considering the empirical study, if it were to be conducted again, service user involvement could considerably strengthen the research. Of course this is dependent upon the availability of resources such as time and money. Time would allow for the recruitment of people with lived experience of psychosis with delusions. Time is also necessary for PPI members to be trained in the intervention and measures. Money is of particular importance as PPI members should be paid for their time and travel, with provision for PPI involvement in dissemination if it occurs outside of the funding timeline.

Mental Imagery

Whilst completing the literature review, it became evident that a lack of consistency in how mental imagery was defined and measured existed. The review did not aim to identify how mental imagery was defined or assessed and so the included research was not systematically selected to explore this. A systematic review would be beneficial in this area as it could categorise how imagery is defined and measured and identify the similarities and differences across mental imagery research. A definition was only provided by Serruya & Grant, (2009) who explained imagery as, “perceptual information that is brought to mind

from memory and imagination rather than arising from activation of the sense organs" (p. 792), attributing this understanding to Kosslyn (1980). The use of psychometric measures was similarly absent. Only one study, Taylor et al., (2020), measured imagery through the Mental Imagery in Psychosis Questionnaire (MIPQ; Taylor et al., 2019, adapted from Holmes et al., 2016), which explores characteristics of mental imagery and the Spontaneous Use of Imagery Scale (SUIS, Reisberg et al., 2003), which measures a person's spontaneous use of imagery in daily life. No other study used psychometric measures of mental imagery and so comparison across samples is not possible. The area of mental imagery research would benefit from clearly stated definitions and more consistently used psychometric measures for general propensity and daily use of imagery e.g., SUIS, or imagery characteristics such as vividness e.g., Vividness of Visual Imagery Questionnaire (Marks, 1973), which would make group comparison easier across studies.

Conclusion

This thesis has explored a growing area of research initially through a literature review of mental imagery interventions, which supports the case series, an imagery-focused intervention for people with psychosis with delusions. This chapter has summarised the results of both papers, alongside the strengths and limitations of each. Key learning points and considerations such as, recruiting online and delivering an intervention via telehealth are reflected upon and considered in relation to existing literature. Despite the limitations present within both papers, they individually provide unique contributions to the literature on psychosis and mental imagery, as well as offering clear clinical implications.

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Section Four: Ethics Proposal

Ethics proposal for the empirical study:

Telehealth delivered iMAgery focused therapy for delusions in PSychosis (iMAPS): A Case Series.

Word count (excluding references, tables and appendices): 5,943

Aimee Cairns

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

April 2022

Faculty of Health and Medicine Research Ethics Committee (FHMREC)
Lancaster University

Application for Ethical Approval for Research

for additional advice on completing this form, hover cursor over 'guidance'.

Guidance on completing this form is also available as a word document

Title of Project: Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis

Name of applicant/researcher: Aimee McMullan

ACP ID number (if applicable)*: **Funding source (if applicable)**

Grant code (if applicable):

***If your project has *not* been costed on ACP, you will also need to complete the Governance Checklist** [link]**.**

Type of study

☐ Involves existing documents/data only, or the evaluation of an existing project with no direct contact with human participants. **Complete sections one, *two* and four of this form**

☒ Includes *direct* involvement by human subjects. **Complete sections one, *three* and four of this form**

SECTION ONE

1. Appointment/position held by applicant and Division within FHM Trainee Clinical Psychologist completing the Doctorate in Clinical Psychology

2. Contact information for applicant:
E-mail: a.mcmullan@lancaster.ac.uk **Telephone**: 07495749449

Address: Doctorate in Clinical Psychology, Health Innovation Centre, Lancaster University, Bailrigg, Lancaster
United Kingdom, LA1 4YG

3. **Names and appointments of all members of the research team (including degree where applicable)**

Dr James Kelly, Lecturer in Research Methods and Principal Clinical Psychologist, ClinPsyD (Lancaster University and Greater Manchester Mental Health NHS Foundation Trust)
Dr Christopher Taylor, ClinPsyD, PhD (Principal Clinical Psychologist and Clinical Lead – Bury Secondary Care Psychological Therapies Service, Pennine Care NHS Foundation Trust)

3. If this is a student project, please indicate what type of project by marking the relevant box/deleting as appropriate: (please note that UG and taught masters projects should complete **FHMREC form UG-tPG**, following the procedures set out on the FHMREC website

PG Diploma ☐ Masters by research ☐ PhD Thesis ☐ PhD Pall. Care ☐

PhD Pub. Health ☐ PhD Org. Health & Well Being ☐ PhD Mental Health ☐ MD ☐

DClinPsy SRP ☐ [if SRP Service Evaluation, please also indicate here: ☐] DClinPsy Thesis ☒

4. Project supervisor(s), if different from applicant:

5. **Appointment held by supervisor(s) and institution(s) where based (if applicable)**: Dr James Kelly, Lancaster University

SECTION TWO

Complete this section if your project involves existing documents/data only, or the evaluation of an existing project with no direct contact with human participants

1. Anticipated project dates (month and year)

Start date: End date:

2. Please state the aims and objectives of the project (no more than 150 words, in lay-person's language):

Data Management

For additional guidance on data management, please go to Research Data Management *webpage, or email the RDM support email:* rdm@lancaster.ac.uk

3. Please describe briefly the data or records to be studied, or the evaluation to be undertaken.

4a. How will any data or records be obtained?

4b. Will you be gathering data from websites, discussion forums and on-line 'chat-rooms'

4c. If yes, where relevant has permission / agreement been secured from the website moderator?

4d. If you are only using those sites that are open access and do not require registration, have you made your intentions clear to other site users?

4e. If no, please give your reasons :

5. What plans are in place for the storage, back-up, security and documentation of data (electronic, digital, paper, etc)? Note who will be responsible for deleting the data at the end of the storage period. Please ensure that your plans comply with General Data Protection Regulation (GDPR) and the (UK) Data Protection Act 2018.

6a. Is the secondary data you will be using in the public domain?

6b. If NO, please indicate the original purpose for which the data was collected, and comment on whether consent was gathered for additional later use of the data.

Please answer the following question *only* if you have not completed a Data Management Plan for an external funder

7a. How will you share and preserve the data underpinning your publications for at least 10 years e.g. PURE?

7b. Are there any restrictions on sharing your data?

8. Confidentiality and Anonymity

a. Will you take the necessary steps to assure the anonymity of subjects, including in subsequent publications?

b. How will the confidentiality and anonymity of articipants who provided the original data be maintained?

Participant identification number will be assigned to each participant. Participants will be asked to note this number on their consent forms. This number, and not the participants' names will be used to identify their data?

9. What are the plans for dissemination of findings from the research?

10. What other ethical considerations (if any), not previously noted on this application, do you think there are in the proposed study? How will these issues be addressed?

SECTION THREE

Complete this section if your project includes *direct* involvement by human subjects

1. Summary of research protocol in lay terms (indicative maximum length 150 words):

Some people think in mental images, seeing pictures in your mind's eye. These images can be positive, negative, a past event or imagined future and often feel real and vivid. Alongside negative beliefs about the self, mental images have been found to maintain persecutory delusions; the strongly held, culturally unacceptable belief that harm is occurring or going to occur. Research suggests that imagery is frequent in psychosis however most people do not receive NICE guideline treatment interventions. Brief interventions targeting specific mechanisms, such as mental imagery, are an important strategy to improve access. Perhaps an accessible, short-form intervention would reduce distressing psychotic experiences.

This study aims to assess how feasible and acceptable an online therapy intervention is for people with psychosis, who experience mental images and persecutory delusions. Participants will complete baseline sessions, six imagery-based therapy sessions with a trainee clinical psychologist and several outcome measures before and after intervention.

2. Anticipated project dates (month and year only)

Start date: 02/2021 End date: 08/2022

Data Collection and Management

For additional guidance on data management, please go to Research Data Management *webpage, or email the RDM support email:* rdm@lancaster.ac.uk

3. Please describe the sample of participants to be studied (including maximum & minimum number, age, gender):

A maximum of 6 participants will be opportunistically recruited from the community, they will be adults aged between 18 and 65, of any gender and have a diagnosis of psychosis, schizophrenia or schizoaffective disorder. Mental health diagnosis such as psychosis will be self-reported by the participant.

Inclusion criteria are: 1) a persecutory delusion currently, or within the past four weeks, meeting criteria outlined by Freeman and Garety (2000; the individual believes that harm is occurring or is going to occur to him or her and the persecutor has the intention to cause harm), 2) identifying a distressing image related to a persecutory delusion, 3) capacity to give informed consent in line with Mental Capacity Act Legislation (2005; see Appendix U), 4) find their reported paranoid beliefs distressing or be help seeking for paranoid or suspicious beliefs, 5) aged 18-65 years, 6) self-reported diagnosis of psychosis, schizophrenia or schizoaffective disorder, 7) Participants will be asked to complete the measures and online imagery intervention in English. If the participants cannot speak English fluently, they will be excluded due to limited funding for translators/interpretation and time restraints to work with data in another language. 8) Participants will be required to have access to a device and internet on which they can access a video-conferencing software (e.g. Teams or Zoom) in order to participate in the online intervention. We are aware of the digital divide this creates, however, are hopeful that it allows access to other minority groups e.g. those with social anxiety, who may not engage in face-to-face therapy. Finally, participants will need access to a space to take part in therapy where they feel safe, cannot be overheard and have their confidentiality maintained.

Exclusion criteria are: 1) moderate/severe learning difficulties, acquired brain injury or neurological impairment, 2) severe substance misuse* 3) experiencing an acute episode requiring in-patient care or 4) currently participating in treatment studies or receiving psychological therapy.

*Substance misuse is deemed severe if it impairs the participants ability to engage with the research and session content. If applicable we will discuss this with the participant and explain that it may not be the right time for therapy. We will also signpost them to services that could offer support e.g. Addaction, a charity that supports people with drug, alcohol or mental health problems (addaction.org.uk).

4. How will participants be recruited and from where? Be as specific as possible. Ensure that you provide the *full versions* of all recruitment materials you intend to use with this application (eg adverts, flyers, posters).

Participants will be recruited online via social media platforms such as Twitter, Reddit and through third sector organisations e.g. Mind and Rethink. Adverts for the study online will include a flyer for the study (Appendices B, C and D) and Participant Information Sheet (Appendix E). The trainee and her supervisors will share tweets with the flyer and participant information sheet on Twitter and ask other professionals to share it. A participant opt-in form will also be included (Appendix F), in which participants are asked for their consent for a member of the team to contact them and discuss the study further, the participant will be asked for their name, signature and email address or contact number. If a participant decides to not participate following this contact all contact and identifying information will be deleted, however, demographic information will be anonymously recorded to describe participants who opted out or drop out of the study. We will ask the participant the reason for withdrawal and record this anonymously with their consent. If a participant is interested in taking part they will be sent the information sheet and consent form (appendix G) and given 24-48 hours to consider their participation. If a participant agrees to take part, a secure video call via Teams or NHS approved "Attend Anywhere" will be arranged. Consent to record the call will be requested and the consent form read out during the call. The docmented video call giving verbal informed consent will act as equivalent evidence of written, informed consent. When informed consent is obtained the trainee clinical psychologist will contact the participant and arrange an initial screening phone call, they will discuss and assess inclusion criteria with the participant (appendix A) and a pre-treatment risk assessment (appendix T).

When the study is fully recruited to online advertisements will cease. If people continue to show interest after the recruitment stage, the research team will thank them for their interest but inform them the study has reached capcity. The researchers will offer the opportunity for the person to be contacted in the future should recruitment reopen, in this case the person's details will be kept securely in an encrypted and password protected spreadsheet until the study has finished.

Participants who are not eligible or contact after recruitment closes will be signposted to other studies that are ongoing such as the UK Clinical Trials Gateway, information on how to access help (appendix R) and a list of resources, including self-help guides, websites and book (appendix S).

5. Briefly describe your data collection and analysis methods, and the rationale for their use.

The primary interest is the feasibility and acceptability of iMAPS therapy online with a community sample of people self-reporting psychosis and distressing persecutory delusions. The proposed is an online case series adapting Taylor et al., 2018. A non-concurrent A-B multiple baseline design will be used. All participants will be randomised to a multiple baseline, minimum of 2 and maximum of 5 baseline sessions. Allocation will be by an independent

researcher at another institution through a web-based randomisation service (Sealed Envelope). Randomisation over various baseline lengths allows treatment effects to be delineated from the effect of time. Randomly allocating participants to number of baseline sessions also helps reduce the risk of bias and strengthen the validity of the research in the abscene of a control group. Furthermore, if a statistical change is found we will be better able to argue it is due to the therapeutic intervention, rather than a natural decline in symptoms and distress. Six intervention sessions will begin at the end of baseline sessions, if there is a stability in delusions. Similar to other multiple baseline designs, stability will be defined as either a stable or worsening clinical presentation based on PSYRATS. If a participant reports improvement of psychotic experiences within the baseline period then the baseline time will be extended to assess if symptoms continue to improve.

Informed consent will be obtained in line with the Mental Capacity Act Legislation (2005; Appendix U) and recorded verbally. The trainee clinical psychologist will email/post the study information sheet and consent form to the participant, after a minimum of 24 hours to consider involvement, the trainee clinical psychologist will contact the participant to obtain consent. The trainee clinical psychologist will read each statement on the consent form (appendix G) to the participant on a video call e.g. Microsoft Teams, the participant's verbal responses will be recorded on the video call. This recording will be stored securely.

Microsoft Teams provides the remote ability to conduct work and share information via a virtual meeting space. To access Microsoft Teams participants do not need to download any software or create an account. Participants will receive a web link from the clinican to enter the virtual space remotely at the time agreed and choose to enter as a "guest". The researcher will have started the meeting and be able to admit the participant into the session. The researcher will ensure they conduct all research activities in an environment that maintains confidentiality i.e. conversations cannot be overheard by others, participants cannot see confidential or personal information in the background, confirming if the participant has a safe and confidential space.

Quantitative data and demographic information (see appendix N) will be collected from questionnaires and structured interview measures completed by participants (listed below). All data will be stored on a password protected SPSS dataset. Questionnaires will be completed online using a web-based survey tool e.g. Qualtrics and collected anonymously. These data will be entered into a database that is password protected. A unique ID code will be created by the participant and entered to distinguish between participants and linked responses. Data will be cached by the survey software. This will be downloaded by the researchers when a participant completes or withdraws from the study, at this point their data on the survey will be permanently deleted from the survey software.

Measures

Completed at all baseline and intervention sessions:

Psychotic Symptom Rating Scales (PSYRATS; Haddock et al., 1999; Appendix H)

Mental Imagery in Psychosis Questionnaire (MIPQ; adapted from Holmes et al., 2016; Appendix O)

Sessional mood rating (Appendix P)

Completed pre- and post- intervention sessions:

Positive and Negative Syndrome Scale Positive subscale (PANSS; Kay et al., 1987; Appendix Q)

The Calgary Depression Rating Scale for Schizophrenia (CDSS; Addington, 1994; Appendix I)

Spontaneous Use of Imagery Scale (SUIS; Reisberg et al., 2003; Appendix J)

Brief Core Schema Scales (BCSS; Fowler et al., 2006; Appendix K)

Working Alliance Inventory (WAI-SR; Hatcher and Gillaspy, 2006; Appendix L)

Completed 2-weeks post therapy:

Adverse Effects in Psychotherapy (AEP; Hutton, 2016; Appendix M)

Diagram of session structure

The diagram below shows the possible configurations of sessions and each participant will be randomised to one of them.

IA = initial assessment; B = baseline sessions; I = intervention session; PA = post-therapy assessment

IA	B	B	I	I	I	I	I	I	PA		
IA	B	B	B	I	I	I	I	I	I	PA	
IA	B	B	B	B	I	I	I	I	I	I	PA
IA	B	B	B	B	B	I	I	I	I	I	I

PA

Data Analysis

Feasibility and acceptability will be assessed by evaluating the number of people interested in participating, number recruited, sessions attended, drop-out rate and adverse effects of therapeutic alliance. Descriptive statistics for all outcome measures will be reported. Visual inspection will establish whether beginning therapy preceded improvements in outcome variables. Effect size will be measured using Cohen's D (Cohen, 1988). A clinically significant change will be identified if there is a ≥25% reduction in PSYRATS delusions from baseline to end of therapy. A 50% reduction will be considered 'much improved' (Durham et al., 2003). All analysis will be conducted using SPSS.

6. What plan is in place for the storage, back-up, security and documentation of data (electronic, digital, paper, etc.)? Note who will be responsible for deleting the data at the end of the storage period. Please ensure that your plans comply with General Data Protection Regulation (GDPR) and the (UK) Data Protection Act 2018.

All files will be encrypted and stored securely on a secure server hosted by Lancaster University or NHS server, in an access restricted folder as it may contain sensitive information. Only the research team based at Lancaster University (AM and JK) will have access to this personal data. Data will be anonymised before any other members of the wider team have access to data. All researchers will ensure personal confidential data is not stored on local hard disks (C:drives), unencrypted memory sticks or other portable media. Confidential data will only be stored in network drives in password protected files or encrypted drives. Anonymised data will be stored for ten years on Lancaster University's secure server, descriptions will be held on a read only file.

This study involves collecting some personal data under the terms of the GDPR (2018): e.g. consent forms will be electronically signed by participants and for 30 days we will have a participant ID linked to the consent forms and digital information to allow for participants to withdraw from the study. This linked data will be stored on a password protected server that has restricted access to only the research team and this personal data linkage will be managed by AM. Following this 30 day period we will break this linkage and all transcript and data will be given a random partipant number (that is not linked to the consent forms personal data or site information).

The following safeguards will be put in place:

- All data collected for this study will be anonymised using unique participant number codes allocated to each participant. Any personal data shared during the course of the intervention

will be redacted and will not be shared outside of the research team, and will not be used or published.

- All files containing sensitive information will be encrypted
- For the first 30 days linkage period, the metadata excel file in which codes are stored will be password protected and stored securely in an encrypted folder on the Lancaster University server. This file will only be accessible by the direct research team.
- Confidential or sensitive documents will not be e-mailed
- Confidential or sensitive documents will not be permitted to be downloaded onto unencryped devices
- Confidential or sensitive documents will not be stored outside of the Lancaster University server

7. Will audio or video recording take place? ☐ no ☒ audio ☒ video

a. Please confirm that portable devices (laptop, USB drive etc) will be encrypted where they are used for identifiable data. If it is not possible to encrypt your portable devices, please comment on the steps you will take to protect the data.

Any identifiable data will be stored on a password protected and encrypted laptop on Lancaster University's secure server. This data will be deleted from the recorder and/or electronic storage as soon as they have been used for supervision purposes. Onedrive on the Lancaster University secure serve and Microsoft Teams will be used for file storage. Files will be password protected and only accessed by the three researchers named on this proposal.

Audio and video recordings will only be used for supervision of the trainee and to ensure fidelity to the clinical intervention (which is common practice on therapy research trials/studies), and not for the thesis or write-up and will be deleted at end of the study.

b What arrangements have been made for audio/video data storage? At what point in the research will tapes/digital recordings/files be destroyed?

All data will be in digital format and only stored on Lancaster university's secure server on password protected files, on password protected computers that will be located in a locked, secure building.

All audio/video data will be deleted following supervision.

Please answer the following questions *only* if you have not completed a Data Management Plan for an external funder

8a. How will you share and preserve the data underpinning your publications for at least 10 years e.g. PURE?

The data generated within this project will be stored in Lancaster University's institutional data repository. Lancaster University uses PURE as the data repository which will hold, manage, preserve and provide access to datasets produced by Lancaster University research.

8b. Are there any restrictions on sharing your data ?

There are no plans to make the data available to individuals outside of the research team.

9. Consent

a. Will you take all necessary steps to obtain the voluntary and informed consent of the prospective participant(s) or, in the case of individual(s) not capable of giving informed consent, the permission of a legally authorised representative in accordance with applicable law? yes

b. Detail the procedure you will use for obtaining consent?

Recruitment advertisements will include a link to participant information sheet (see appendix E), consent forms (see appendix G) and participant opt-in form (see appendix F). Participant opt-in sheets allow participants to give consent to be contacted by the researcher to further discuss the study. Upon receipt of this form the researcher (Aimee McMullan) will contact the potential participant to discuss the study, inclusion criteria and will provide them with the participant information sheet and consent form. The researcher will then allow the potential participant between 24 and 48 hours to consider their participation in the study. If the participant consents to take part the researcher will set-up a telephone or online meeting to screen the participant in line with inclusion criteria.

The information sheet which provides an overview of the study, nature of the intervention, confidentiality and data storage. The intervention will be scheduled to take place over 8 to ~~13 weeks~~ 26weeks for between one to one and a half hours per week, per participant depending on the stage of therapy. Consent will be taken verbally and via email confirmation due to the online nature of the study. Throughout baseline and intervention sessions participants will be reminded that their participation is voluntary, and participants are free to withdraw at any time during or after the data collection (up to the end of the study, i.e. the submission of the thesis and submission of the peer review publication), with information regarding who to contact and how withdrawing works discussed.

Participants will be fully briefed as to the purpose of the research and confidentiality will be assured except in the case a risk to self, risk to others or safeguarding disclosure is made. All briefings will outline confidentiality alongside the limitations of this i.e. confidentiality is ensured unless the participants discloses harm/intended harm to self or others.

10. What discomfort (including psychological eg distressing or sensitive topics), inconvenience or danger could be caused by participation in the project? Please indicate plans to address these potential risks. State the timescales within which participants may withdraw from the study, noting your reasons.

Limitations of confidentiality: Participants will be made fully aware of confidentiality and the anonymity of their information. The participants will be informed that researchers will follow confidentiality guidelines, including their duty to act on any disclosures regarding the participants risk to self or others. If there is a safeguarding concern the trainee clinical

psychologist will discuss, where possible, how they will break confidentiality with the participant, i.e. inform the research team and the participants GP following the risk protocol.

Minimising possible distress of participants:

The intervention will be conducted sensitively by a trainee clinical psychologist with extensive research experiene with mental health service users. If required, participants will be offered opportunities to pause or stop the intervention. All participants will be provided with information about sources of support (Appendices R and S). A senior member of the research team will supervise the trainee clinical psychologist on a weekly basis. Any potential risk issues or change in risk will be discussed with the supervisory team (two clinical psychologists). Each participant will receive signposting information (Appendix R) and a distress protocol will be developed.

To minimise potential distress experienced by the participant in an online and remote setting the reseracher (AM) will complete eligibility and risk screening assessment at the initial assessment session (see appendix T). This includes a management plan that will be completed collaboratively with the participant. The management plan will include; relevant crisis management plan, contact information of people in case of emergency, names and contact information of individuals aware of the participants involvement in the study, detail any safeguarding issues and action plans for these. We will also discuss coping strategies with the participant. If there are any concerns the researcher will contact her supervisors (JK and CT) to discuss further and seek clinical guidance.

Minimising tasks for participants: there are a large number of measures, these were found to be acceptable by Taylor et al., (2020). We will trial completing the measures with service users and gather feedback on the feasibility of completing all measures. If the service users experience fatigue effects, we will cut the CDSS (Addington, 1994, appendix I) from the battery of measures.

11. What potential risks may exist for the researcher(s)? Please indicate plans to address such risks (for example, noting the support available to you; counselling considerations arising from the sensitive or distressing nature of the research/topic; details of the lone worker plan you will follow, and the steps you will take).

The researcher conducting the intervention and collecting data will keep a register of any disclosures or incidents that occur throughout the research and these will be discussed with and managed by the research team supervisors. The researcher conducting the intervention will be provided with regular supervision and debriefing with their research supervisors to discuss distressing or upsetting content or experiences whilst working on the research project. The potential risk associated with this population is not above or beyond what the researcher is already experienced with and expected to deal with in their usual, clinical work at doctoral level.

12. Whilst we do not generally expect direct benefits to participants as a result of this research, please state here any that result from completion of the study.

Participants will receive psychoeducation and practice therapeutic imagery techniques with an aim to reduce persecutory delusions.

13. Details of any incentives/payments (including out-of-pocket expenses) made to participants:

There are no incentives or payments associated with this study.

14. Confidentiality and Anonymity

a. Will you take the necessary steps to assure the anonymity of subjects, including in subsequent publications? yes

b. Please include details of how the confidentiality and anonymity of participants will be ensured, and the limits to confidentiality.

All participants will be provided with an information sheet (appendix E) which provides an overview of the study, nature of the intervention, confidentiality and data storage. Throughoug the duration of the intervention participants will be reminded that their participation is voluntary, and participants are free to withdraw at any time during or after data collection with information regarding who to contact and how to withdraw.

Participants will be fully briefed as to the purpose of the research and confidentiality will be assured except in the case a disclosure is made. Participants will be informed that confidentiality will be broken if they disclose harm to themselves or others and the process will be discussed where possible. A pre-intervention risk assessment (appendix T) has been developed and will be completed with participants.

Confidentiality will be maintained by ensuring that any formation that could identify participants will be anonymised and the participant's names will occur only on their consent forms. We will comply with GDPR (2018), Human Rights Act (1998) and Freedom of Information Act (2005). Informed consent will be obtained from all participants. Participants will be informed at the start of the recruitment process and through an information sheet about their rights to withdraw from the study. If the participants withdraw from the study all information pertaining to them will be destroyed including any recordings. The process of sharing information with third parties will be discussed with each participant.

Audio Recordings:

Recorded data generated from this research project will be kept on Lancaster University's secure server, on a password protected laptop and destroyed following supervision. Recorded data will only be used to ensure fidelity to the intervention by the researcher and her supervisor on a weekly basis. Data will be deleted at end of the study. No identifiable information will be released at any stage of the research project including dissemination of the research findings.

15. If relevant, describe the involvement of your target participant group in the *design and conduct* of your research.

Service user involvement groups (e.g. Hearing Voices, National Paranoia Network and Lancaster University Public Involvement Network), will be asked to be involved in the desgin of the study by sense checking the idea of mental imagery, testing the number of questionnaires in our battery and we will discuss dissemination ideas with the group to ensure information is accessible.

16. What are the plans for dissemination of findings from the research? If you are a student, include here your thesis.

Data produced by this study will be owned by Lancaster University. Upon completion, the data will be analysed and tabulated and a thesis prepared. A full thesis will be published on the Lancaster Univeristy Library and will be accessible by academics, students and members of the public,

In addition to the thesis write-up we will also aim to develop the following outputs to disseminate the findings of the study:

- Journal publication e.g. Cognitive Therapy and Research, Behavioural Cognitive Psychotherapy or Psychology and Psychotherapy: Theory, Research and Practice
- Publications available to general public/service users e.g. mental health today, asylum magazine
- Sector magazines e.g. BPS, BMJ
- Seminar presentation
- Blog post to ensure findings are more accessible given the exclusion created by journal paywalls

As well as publishing academic papers we will include details for participants to be provided with more information about the findings and publications from the study by providing links and contact details for the research team who will assist with providing copies of summaries and updates about the study.

17. What particular ethical considerations, not previously noted on this application, do you think there are in the proposed study? Are there any matters about which you wish to seek guidance from the FHMREC?

N/A

SECTION FOUR: signature

Applicant electronic signature: Aimee McMullan
Date 15/10/2020

Student applicants: please tick to confirm that your supervisor has reviewed your application, and that they are happy for the application to proceed to ethical review ☒

Project Supervisor name (if applicable): Dr James Kelly (Lancaster University, primary supervisor) and Dr Christopher Taylor Date application discussed 15/10/2020

Submission Guidance

1. Submit your FHMREC application by email to Becky Case (fhmresearchsupport@lancaster.ac.uk) as two separate documents:
    i. **FHMREC application form.**
    Before submitting, ensure all guidance comments are hidden by going into 'Review' in the menu above then choosing *show markup>balloons>show all revisions in line.*
    ii. **Supporting materials.**
    Collate the following materials for your study, if relevant, into a single word document:
        a. Your full research proposal (background, literature review, methodology/methods, ethical considerations).
        b. Advertising materials (posters, e-mails)
        c. Letters/emails of invitation to participate
        d. Participant information sheets
        e. Consent forms
        f. Questionnaires, surveys, demographic sheets
        g. Interview schedules, interview question guides, focus group scripts
        h. Debriefing sheets, resource lists

    Please note that you DO NOT need to submit pre-existing measures or handbooks which support your work, but which cannot be amended following ethical review. These should simply be referred to in your application form.

2. Submission deadlines:
    i. Projects including direct involvement of human subjects **[section 3 of the form was completed]**. The *electronic* version of your application should be submitted to Becky Case **by the committee deadline date.** Committee meeting dates and application submission dates are listed on the FHMREC website. Prior to the FHMREC meeting you may be contacted by the lead reviewer for further clarification of your application. Please ensure you are available to attend the committee meeting (either in person or via telephone) on the day that your application is considered, if required to do so.
    ii. The following projects will normally be dealt with via chair's action, and may be submitted at any time. **[Section 3 of the form has *not* been completed, and is not required].** Those involving:
        a. existing documents/data only;

b. the evaluation of an existing project with no direct contact with human participants;
c. service evaluations.

3. **You must submit this application from your Lancaster University email address, and copy your supervisor in to the email in which you submit this application**

Faculty of Health and Medicine Research Ethics Committee (FHMREC)

Lancaster University Application for Amendment to Previously Approved Research

1. Name of applicant:

Aimee McMullan

2. E-mail address and phone number of applicant:

a.mcmullan@lancaster.ac.uk

3. Title of project:

Exploring the Feasibility and Acceptability of Online Imagery Focused Techniques for People with Psychosis

4. FHMREC project reference number:

FHMREC20025

5. Date of original project approval as indicated on the official approval letter (month/year):

16/12/2020

6. Please outline the requested amendment(s)
Note that where the amendment relates to a change of researcher, and the new researcher is a student, a full application must be made to FHMREC

Extend maximum time of intervention from 13 weeks to 26 weeks.

7. Please explain your reason(s) for requesting the above amendment(s).

A participant currently taking part in the study has requested 2 weeks between sessions rather than the weekly sessions we had initially planned as a research team. The participant stated this would allow time to practice strategies discussed between sessions. I agree with the participant and this is something that myself and supervisors accommodate clinically within the NHS. I feel it is important that our maximum time of intervention is extended to ensure we are working in a person-centred way.

By extending the maximum time from 13 weeks to 26 weeks participants could do sessions fortnightly rather than weekly. The participant who requested this feels this would be beneficial to practice strategies between sessions. It also offers flexibility to the participant should they have to reschedule or cancel, something very important especially in the current situation with COVID-19 and suddenly finding yourself isolating or caring for those isolating.

Guidance:

a) Resubmit your research ethics documents (**the entire version which received final approval, including all participant materials, your application form and research protocol**), with all additions highlighted in yellow, and any deletions simply 'struck through', so that it is possible to see what was there previously.
b) This should be submitted as **a single PDF** to Becky Case There is no need to resubmit the Governance Checklist

Applicant electronic signature: Date

Aimee McMullan	Click or tap to enter a date.

Student applicants: please tick to confirm that you have discussed this amendment application with your supervisor, and that they are happy for the application to proceed to ethical review ☒

Project Supervisor name (if applicable): Date application discussed

	Click or tap to enter a

You must submit this application from your Lancaster University email address, and copy your supervisor in to the email in which you submit this application

Ethical Approval Letter

Applicant: Aimee McMullan
Supervisor: James Kelley, Christopher Taylor
Department: DHR
FHMREC Reference: FHMREC20178 (Amendment to FHMREC20025)

15 July 2021

Re: FHMREC20178

Exploring the Feasibility and Acceptability of Online Imagery Focused Techniques for People with Psychosis

Dear Aimee,

Thank you for submitting your research ethics application for the above project for review by the **Faculty of Health and Medicine Research Ethics Committee (FHMREC)**. The application was recommended for approval by FHMREC, and on behalf of the Chair of the Committee, I can confirm that approval has been granted for this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer at the email address below (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information. Email:

fhmresearchsupport@lancaster.ac.uk

Yours sincerely,

[redacted]

Tom Morley,
Research Ethics Officer, Secretary to FHMREC.

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Appendix A: Research Proposal

Research Proposal

Title

Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis

Name of applicant/supervisors/affiliations

Aimee McMullan
Trainee Clinical Psychologist, Lancaster University
Dr James Kelly
Clinical Psychologist, Lecturer in Research Methods (DClinPsy), Lancaster University
Dr Christopher Taylor
Clinical Psychologist, Clinical Lead – Bury Secondary Care Psychological Therapies (ClinPsyD, PhD), Pennine Care NHS Foundation Trust

Introduction

Psychological models of psychosis suggest psychotic symptoms such as hallucinations and delusions can be developed and maintained by negative schematic beliefs (Morrison, 2004). Negative schemas have been defined as stable negative beliefs about the self and others which influence interpretations of specific situations, these are common in people with psychosis. Approximately 50% of people who experience persecutory delusions have levels of psychological well-being within the lowest 2% of the general population (Freeman et al., 2014). Delusions are usually experienced alongside depression, anxiety, and disrupted sleeping patterns (Freeman, 2016).

The National Institute for Health and Care Excellence (NICE, 2014), recommends Cognitive Behavioural Therapy for adults with psychosis. However, treatment effects of first-generation CBT for Psychosis are often small (Jauhar et al., 2014) with inconsistent outcomes. Research suggests targeting individual symptoms such as paranoia may be beneficial (Bentall 2003), specific symptoms may be caused and maintained by specific processes. Mental images may reduce distress in psychosis (Taylor et al., 2020). Mental images are described as ‘seeing with the mind’s eye’, subjective sensory perceptions that may

drive behaviour and elicit greater emotional responses (Holmes & Mathews, 2010). Schulze et al., (2013), found that a substantial proportion of people (72.5%) with a diagnosis of psychosis experienced mental images and reported that images provoked anxiety and distressing persecutory delusions, this was also evidenced by Morrison et al (2004). Previous mental imagery literature focused on mood disorders, but recent research indicates an overlap with psychosis in terms of behavioural and cognitive maintenance factors. It is possible that these factors could be targeted by similar treatment interventions. For example, anxiety symptoms commonly co-occur with persecutory thoughts, and Taylor et al., (2019), identified intrusive, anxiety provoking mental images as key features of psychosis.

Treatment interventions with an imagery focus are reportedly effective within anxiety disorders and could potentially offer a novel approach to addressing anxiety provoking mental images in psychosis. Imagery re-scripting has been found to effectively reduce distress and a person's pre-occupation with unhelpful schemas in several studies (Arntz & Jacob, 2012; Morrison et al., 2004). Taylor et al., (2019) published a six-session approach that used the following techniques: imagery re-scripting of past events, imagery suppression and creating positive imagery. Five participants with first-episode psychosis completed the study, results showed a significant reduction in delusions, imagery distress and negative schematic beliefs. The proposed study will build upon Taylor et al., by delivering a similar imagery-based intervention online to individuals with psychosis. Participants will be recruited via social media and self-referral, not the NHS. Imagery re-scripting assists an individual to mentally transform a distressing, problematic image into a more positive, less threatening image (Taylor et al., 2019). Imagery re-scripting begins with entering an image from an observer perspective, viewing it as an outsider, and then returning to the image from a third person perspective. Research has suggested that this technique reduces negative affect and does not elicit overwhelming or strong emotional responses (Ison et al., 2014).

In the current global pandemic, there has been a substantial shift to delivering therapy online and this research will explore the acceptability and feasibility of an online treatment approach. Schrank et al., (2010) found that people with psychosis used the internet at similar rates to non-clinical populations. Their research indicated that people with psychosis found it assisted them in overcoming difficulties around social interaction. Several meta-analyses have found online interventions to be effective in the treatment of depression and anxiety (Spek et al., 2007), however there is a lack of research applying treatments online in psychosis populations, making this research timely and necessary. A systematic review by

Alvarez-Jimenez (2014) concluded that people with psychosis had seemingly found internet and mobile-based interventions to be acceptable and feasible.

Research Questions

This research will formally test the feasibility and acceptability of an imagery-focused approach online for individuals who self-report persecutory delusions. It will explore the impact of the approach on imagery characteristics and persecutory delusions. This involves examining if participants can be recruited to a case series study, how many participants complete sessions, drop-out, reasons for drop-out, gathering feedback on intervention and any adverse effects of therapy.

Is an online imagery-focused intervention designed to reduce paranoia in people with psychosis:

- Feasible, i.e. is it possible to recruit and collect data as planned?
- Acceptable, i.e. do participants find the intervention suitable, how many sessions do they attend, how many participants complete the therapy?
- How does it impact reported distress caused by images?

Method

Design

The proposed method is an online case series, non-concurrent A-B multiple baseline design adapting Taylor et al., 2020, this is an established strategy for developing treatments. Participants will be randomised to multiple baselines; minimum 2 and maximum 5 sessions, six online-intervention sessions and an end-of-intervention session. Differing baselines delineate treatment effects from effect of time. Randomly allocating participants to number of baseline sessions also helps reduce the risk of bias and strengthen the validity of the research in the absence of a control group. Furthermore, if a statistical change is found we will be better able to argue it is due to the therapeutic intervention, rather than a natural decline in symptoms and distress. Interventions will begin following the baseline period if the participant has stability in their delusions, defined by either a stable or worsening clinical presentation based on PSYRATS Delusions Scale (Haddock et al., 1999). In the event a participant reports improved psychotic experiences within the baseline period, it will be extended to assess if symptoms continue to improve.

The six-session intervention will begin with psychoeducation about mental images, identifying images and negative schematic beliefs. A maintenance formulation will be

developed collaboratively within the first two sessions. Therapeutic techniques will include: creating safe place imagery; this invites the participant to imagine a place where they feel safe, calm and comfortable (Hackmann et al., 2011), and imagery rescripting; this approach has been developed to help clients mentally alter problematic mental images into new, positive and nonthreatening images (Arntz and Jacob, 2012). The therapist will draw from the following interventions; imagery suppression experiments, behavioural experiments, manipulation of images, creation of positive imagery, working with night-time imagery.

I will receive training and supervision throughout from Dr Taylor (developer of iMAPS, Principal Clinical Psychologist) and Dr Kelly (Principal Clinical Psychologist, BABCP Accredited). We will collaboratively adapt iMAPS for online delivery.

Participants

A maximum of six participants will be recruited, inclusion criteria: 1) a persecutory delusion currently, or within the past four weeks, meeting criteria outlined by Freeman and Garety (2000; the individual believes that harm is occurring or is going to occur to him or her and the persecutor has the intention to cause harm), 2) identifying a distressing image related to a persecutory delusion, 3) capacity to give informed consent, 4) find their reported paranoid beliefs distressing or be help seeking for paranoid or suspicious beliefs, 5) aged 18-65 years, 6) self-reported diagnosis of psychosis, schizophrenia or schizoaffective disorder, 7) Participants will be asked to complete the measures and online imagery intervention in English. If the participants cannot speak English fluently, they will be excluded due to limited funding for translators/interpretation and time restraints to work with data in another language. 8) Participants will be required to have access to a device and internet on which they can access a video-conferencing software (e.g. Teams or Zoom) in order to participate in the online intervention. Participants will need access to a space to take part in therapy where they feel safe, cannot be overheard and have their confidentiality maintained.

Exclusion criteria are: 1) participants with moderate/severe learning disability, acquired brain injury or neurological impairment, 2) severe substance misuse*, 3) experiencing an acute episode requiring in-patient care, 4) currently participating in treatment studies or receiving psychological therapy.

*Substance misuse is deemed severe if it impairs the participants ability to engage with the research and session content. If applicable, we will discuss this with the participant and explain that it may not be the right time for therapy. We will also signpost them to

services that could offer support e.g. Addaction, a charity that supports people with drug, alcohol or mental health problems (addaction.org.uk).

Materials

Demographics: participants will be given a form asking them to report age, gender, ethnicity and occupation. Responses to this, and all surveys, will be coded by an anonymous participant identification number and remain confidential.

Baseline and intervention measures:

The measures will be used at each baseline session (minimum 2, maximum 5 sessions) and at the beginning of each therapeutic intervention session (n=6).

Psychotic Symptom Rating Scales (PSYRATS; Haddock et al., 1999). The PSYRATS has two subscales: 11-item auditory hallucinations and 6-item delusion scales both rated from 0-4 and research indicates excellent inter-rater reliability.

Mental Imagery in Psychosis Questionnaire (MIPQ; Taylor et al., 2019). The MIPQ consists of five questions exploring attributes of a person's mental images. There are two additional questions exploring impact of image on mood and helpfulness of image. All questions are rated on a 10-point Likert scale from 1-10 (1=not at all, 10=extremely).

Sessional Mood Rating. This will be one question, "how would you rate your mood today, with 0 being the worst it has ever been and 10 being the best?", asked by the trainee clinical psychologist at the beginning of each session.

Pre- and post- intervention measures

Positive and Negative Syndrome Scale – positive subscale (PANSS; Kay et al., 1987). PANSS is a measure widely used to assess the symptoms of schizophrenia. The positive scale consists of 7 items and people will be scored from 1 to 7 on each item in a clinical interview. The trainee clinical psychologist will receive training from supervisors in delivery and scoring of the PANSS.

The Calgary Depression Rating Scale for Schizophrenia (CDSS; Addington, 1994). The CDSS is a clinical interview and consists of nine items that assess depression in people with schizophrenia, psychosis or psychotic-like experiences. Participants respond by indicating if the symptom was absent, mild, moderate or severe (0-3 ordinal scale).

Spontaneous Use of Imagery Scale (SUIS, Reisberg et al., 2003). The SUIS is a 12-item self-report scale used to measure the spontaneous use of mental imagery in daily life and focuses only on visual imagery.

Brief Core Schema Scales (BCSS; Fowler et al., 2006). The BCSS aims to assess beliefs about the self and others that are assessed on a five-point rating scale (0-4) across 24, self-report items.

Working Alliance Inventory-Short Revised (WAI-SR; Hatcher & Gillaspy, 2006). The WAI-SR assesses participants views of the therapeutic relationship across 12, self-report items on a 5-point Likert scale.

2-weeks post intervention:

Adverse Effects in Psychotherapy (AEP; Hutton, 2016). The AEP is a self-report measure that asks participants to score their agreement (5-point Likert scale) with 28-items regarding a range of potential adverse events in psychotherapy.

Procedure/Therapy Protocol

Phase of Treatment	Main Approach
Session 1: Assessment, goals, and psychoeducation	Collaboratively decide on if camera will be on for all sessions Define mental imagery, initial assessment: overview of distressing images reported by client, psychotic experiences, persecutory delusions, voices, core schemas, early maladaptive schemas and schema mode. Brief handout that reiterated some of the topics discussed in session Between-session task: adapted imagery diary
Session 2: Formulation and Safe Place Imagery	Develop collaborative formulation Safe place imagery introduces individuals to imagery work, with the goal to provide a place of comfort, support, and relaxation.
Session 3, 4 and 5	Informed by collaborative formulation

	Key approaches that will be used: - Image suppression and responding differently - Manipulation of images - Imagery-related behavioural experiments - Imagery re-scripting and flash-forwards
Session 6: Final sessions	Review imagery characteristics and discuss strategies that were helpful/unhelpful, adaptations to images
Conclusion	Therapy summary booklet – collaboratively designed with client

Proposed analysis

Feasibility and acceptability assessed by evaluating number of sessions attended, drop-out rate, adverse effects of therapy, therapeutic alliance. Descriptive statistics reported for all outcome measures. Visual inspection will establish whether beginning therapy preceded improvements in outcome variables. Effect size measured using Cohen's D (Cohen, 1988), rather than *d* as these are not independent samples. Clinically significant change will be identified by ≥25% reduction in PSYRATS delusions from baseline session to last intervention session, 50% reduction considered 'much improved,' total score for the delusion's subscale. Analysis conducted using SPSS.

Practical issues:

A practical issue that may hinder the project is recruitment, therefore, recruitment will begin as soon as ethical approval is obtained, and the trainee clinical psychologist has been fully trained. This allows time for researchers to contact as many 3rd Sector services and charities as possible, as well as increasing the presence of the study on social media channels. The researcher will contact potential participants via email or telephone to have a conversation before obtaining informed consent and beginning the intervention, this allows time for introductions and a rapport to be established.

The trainee clinical psychologist will receive training in the intervention from Dr Christopher Taylor, developer of iMAPS as part of an NIHR funded project. The trainee will also receive frequent supervision from Dr Taylor and recordings of sessions will ensure fidelity.

We do not anticipate significant logistical issues associated with this research as it is conducted remotely via video-conferencing software. Although, this will mean participants need to access the internet and a device that can support video-conferencing software (e.g. Teams or Zoom) via Wi-Fi or mobile data at their own cost. This may reduce the accessibility of the study, but this is justified as we are developing an online intervention. Which, if found to be acceptable and feasible, will only be available to people with access. However, depending on the quality of the video call, we anticipate an hour would use approximately 225MB.

Data storage has been carefully considered and will comply with all GDPR guidelines and Lancaster University's policy. Data will be anonymised and stored on Lancaster University's secure server on an encrypted and password-protected device.

Ethical concerns:

Limitations of confidentiality: Participants will be made fully aware of confidentiality and the anonymity of their information. The participants will be informed that researchers will follow confidentiality guidelines, including their duty to act on any disclosures regarding the participants risk to self or others. If there is a risk or safeguarding concern the trainee clinical psychologist will discuss, where possible, how they will break confidentiality with the participant, i.e. inform the research team and the participants GP following the risk protocol.

Possible distress of participants: It is not expected that the intervention will cause any distress. The intervention will be conducted sensitively by a trainee clinical psychologist with extensive research experience with mental health service users. If required, participants will be offered opportunities to pause or stop the intervention. All participants will be provided with information about sources of support (appendix R and S). A senior member of the research team will supervise the trainee clinical psychologist on a weekly basis. Any potential risk issues or change in risk will be discussed with the supervisory team (two clinical psychologists). Each participant will receive signposting information (Appendix R) and a distress protocol will be developed as part of the pre-treatment risk assessment (Appendix T)

Minimising tasks for participants: The number of measures was found to be acceptable by Taylor et al., (2020) in a face-to-face trial. As this is an online intervention, we will trial completing the measures with a service user consultant and gather feedback on the

feasibility of completing all measures. If the services users experience fatigue effects, we will cut the CDSS (Addington, 1994; Appendix I) from the battery of measures.

Potential risk to researcher: The researcher conducting the intervention will be provided with regular supervision and debriefing from their research supervisors to discuss distressing or upsetting content or experiences whilst working on the research project. The potential risk associated with this population is not above or beyond what the researcher is already experienced with and expected to deal with in their usual, clinical work at doctoral level.

Timescale

2020

July–September

- Thesis proposal reviewed
- Thesis contract agreed

October-December

- Submit ethics proposal
- Contact groups about recruitment
- Intervention training

2021

January-March

- Obtain ethical approval
- Systematic literature review

March-August

- Draft introduction, method of empirical paper
- Recruit participants, collect data

September-October

Analyse data

October

- Complete analysis

- Draft empirical paper

2022

January-March

- Write thesis findings
- Submit paper for publication
- Begin dissemination

April-August

- Viva examination
- Thesis corrections

References:

Addington J., & Maticka-Tyndale E. (1994). Specificity of the Calgary Depression Scale for schizophrenics. *Schizophrenia Research, 11*(3),239-44

Alvarez-Jimenez, M., Alcazar-Corcoles, M. A., Gonzalez-Blanch, C., Bendall, S., McGorry, P. D., & Gleeson, J. F. (2014). Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. *Schizophrenia research*, *156*(1), 96-106.

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Bentall, R. P., & Swarbrick, R. (2003). The best laid schemas of paranoid patients: autonomy, sociotropy and need for closure. *Psychology and Psychotherapy, 76*(2), 163-171.

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Appendix B: Advertising Materials

Exploring the Feasibility and Acceptability of Online Imagery Focused Techniques for People with Psychosis

We would like to investigate an online intervention for people with psychosis in the community, who experience mental images and suspicious thoughts and beliefs.

Who can participate?

Do you become distressed by paranoid beliefs or do you wish to seek help for paranoia or suspicious beliefs?

Do you currently experience suspicious thoughts and beliefs?

Can you identify an image that comes to your mind that causes you distress?

Have you ever been diagnosed with Psychosis, Schizophrenia or Schizoaffective Disorder?

Are you between 18 and 65 years old?

Do you have reliable access to internet connection and a device that supports video conferencing e.g. Teams or Zoom?

Do you have access to a safe and confidential space for therapy sessions?

What would you be asked to do?

- Initial assessment session = 1 hour
- Baseline sessions (min 2, max 5) = 10-30mins each
- 6 online-therapy intervention sessions = 1 hour
- Questionnaires before, after and during therapy to see if you found the online format feasible and acceptable.

All sessions will be over Teams or Zoom with a trainee clinical psychologist. Intervention sessions will use a range of imagery techniques

If you are interested, please contact:

Aimee McMullan (a.mcmullan@Lancaster.ac.uk)

Lancaster University

Appendix C: Online invites to participate

Email to organisation manager/staff for distribution

*Email Subject: Research opportunity: Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis

Dear [NAME],

RE: Participation in research study

We would like you to participate in a research study exploring if it is acceptable and feasible to deliver an online intervention for people with psychosis.

You would be asked to attend between 2 and 5 baseline sessions online and six therapy sessions online with a trainee clinical psychologist.

More details are available in the attachments. If you have any queries or you are interested in taking part, please contact Aimee McMullan (trainee clinical psychologist) on a.mcmullan@lancaster.ac.uk.

Many thanks,

Aimee

Aimee McMullan
Trainee Clinical Psychologist
Lancaster University
a.mcmullan@lancaster.ac.uk

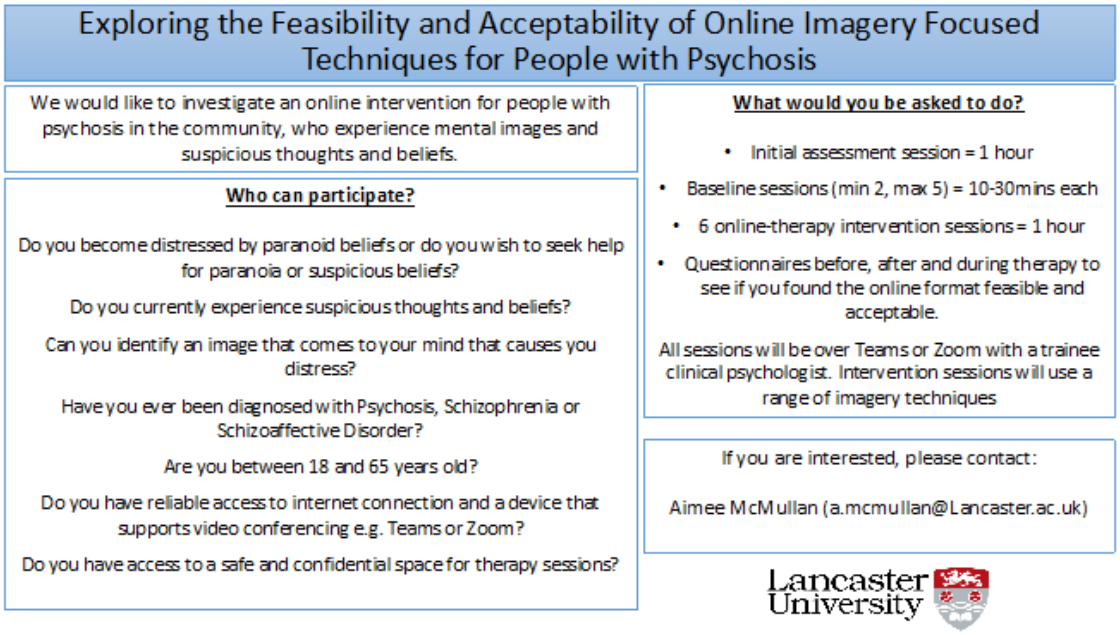
Lancaster University

Appendix D: Recruitment Tweet

To be tweeted out as text:

"New research study using online imagery focused techniques for people with psychosis. Now recruiting for online intervention delivered by trainee clinical psychologist"

Include below as an image:



Appendix E: Participant information sheet

Participant Information Sheet

Lancaster University

Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

My name is Aimee McMullan and I am conducting this research as a student in the Doctorate in Clinical Psychology programme at Lancaster University.

What is the study about?
We would like to find out how feasible and acceptable an online intervention is for people with psychosis in the community, who experience mental images and persecutory delusions.

Why have I been approached?
You have been approached as a person with psychosis, who has/had thoughts that others intend to harm you.

Do I have to take part?
No. It's completely optional, it's up to you whether you would like to take part. You can also decide to take part and then change your mind.

What will I be asked to do if I take part?
If you decide you would like to take part, you would be asked to take part in an initial assessment session lasting approximately one hour. If you are eligible then you would be asked to complete a number of baseline sessions, a minimum of two and maximum of five sessions, these last approximately 30 minutes. These are followed by six therapy sessions delivered online with a trainee clinical psychologist and will last approximately one hour. Finally, there will be a post-therapy session lasting approximately one hour. Sessions will be recorded for supervision purposes and deleted at the end of the study. These sessions will use a range of imagery techniques and you will be asked to complete questionnaires before, after and during the intervention.

What will I need to take part?
You will need to have internet access (or a smartphone with a data allowance) and a device that you can connect to an online video-conferencing platform e.g. Teams or Zoom. You will also need access to a safe space that is private where you cannot be overheard and is confidential.

Will my data be Identifiable?

The information you provide will be kept confidential and stored safely. Your personal information will be kept securely and destroyed at the end of the project. Only the researchers conducting this study will be able to access the data.

- The files on the computer will be encrypted (that is no-one other than the researcher will be able to access them) and the computer itself password protected
- At the end of the study, all electronic information, such as questionnaire responses, will be stored anonymously and securely by the university for 10 years
- All your personal data will be confidential and stored separately from your questionnaire responses
- Recordings of sessions will only be used for supervision of the trainee clinical psychologist and ensuring model fidelity, they will be permanently deleted following completion of the study

There are some limits to confidentiality: throughout the study if you mention something that makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and speak to a member of staff about this. If possible, I will tell you if I have to do this.

What if I change my mind?

You do not have to take part in this study. You will have at least 24 hours to think about whether or not you wish to take part. If you agree to take part, you may stop at any time without giving any reason. At the end of the study, the researcher will write to everyone who took part with a questionnaire. You will still be sent this if you withdraw. In any case, it is up to you if you complete the questionnaire or not.

What will happen after I take part?

The results will be written up into a research report and may be submitted for publication in an academic journal. We would like people to be able to access the results easily so we may write a blog post or do a presentation. You and your information will not be identifiable in any published or presented work. If you would like a copy of the results, please ask the researchers.

Are there any risks?

We do not expect there to be any risk to you by taking part in this study. Some people may experience distress in relation to their mental image distressing. However, using techniques from the intervention, we aim to minimise negative emotions associated with this imagery. If you experience any distress during or after participating, please discuss it with Aimee (the trainee clinical psychologist), or the resources provided at the bottom of this sheet.

Are there any benefits to taking part?

We are investigating a new way of working with persecutory thoughts. This intervention was found to be effective previously in face-to-face therapy, but we do not know how effective it is when delivered online.

Who has reviewed the project?
This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.

How do I take part?
If you are interested in taking part, then you can contact Aimee McMullan at a.mcmullan@lancaster.ac.uk. Aimee is a Trainee Clinical Psychologist and a member of the research team. Aimee will be able to give you more information about taking part

Research team
The research team has three members:

Aimee McMullan (Trainee Clinical Psychologist, Lancaster University)
a.mcmullan@lancaster.ac.uk

Dr James Kelly (Clinical Psychologist, Researcher, Lancaster University)
j.kelly@lancaster@ac.uk 01524 593 535

Dr Christopher Taylor (Clinical Psychologist, Researcher, Pennine Care NHS Foundation Trust)

Complaints
If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Ian Smith Tel: 01524 592282
Consultant Clinical Psychologist; Email: i.smith@lancaster.ac.uk
Department of Health Research
Lancaster University
Lancaster
LA1 4YG

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Dr Laura Machin Tel: +44 (0)1524 594973
Chair of FHM REC Email: l.machin@lancaster.ac.uk
Faculty of Health and Medicine
(Lancaster Medical School)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.

GDPR

"Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if It's inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage:
www.lancaster.ac.uk/research/data-protection"

Lancaster University is the sponsor for the study based in England. 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 responsibly for looking after your information and using it properly. Lancaster University will keep identifiable information about you for 10 years after the study has finished/is published.

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.

Aimee McMullan will collect information from you for this research study in accordance with our instructions.

Aimee McMullan will use your name and contact details to contact you about the research study, to oversee the quality of the study. Individuals from Lancaster University and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Lancaster University who will have access to information that identifies you will be people who need to contact you to audit the data collection process.

Appendix F: Participant Opt-In Form

Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis If you are interested in taking part in this study and would like the researchers to contact you, please give your details below. You should only provide the information if you are happy to be contacted in that way. For example, if you do not want to be contacted by phone then do not provide a phone number.

Please note the following points in relation to the processing of your data:

- Data will be held securely by the research team on behalf of Lancaster University according to the University's data protection and information security policies
- Access to the data will be restricted to the research team for the sole purpose of contacting you about this study
- Your data will not be shared with any third party without your written permission
- The details collected will only be stored for as long as required to find out if you wish to take part in the study. Once no longer needed, that data will be destroyed securely
- If you decide to change your mind about being contacted about the study or would like your details to be destroyed, you can contact *Aimee McMullan* on the details below

Once you have completed your details please add your signature electronically, and email to Aimee McMullan on a.mcmullan@lancaster.ac.uk

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I would like to be contacted further about this research project and I am happy to provide my personal details so that I can be contacted about this study:

Name:	
Signature (can type this in):	
Today's date:	

Contact by phone	Preferred contact number:	
	When would you prefer to be contacted?	Morning/ Afternoon/ Evening/ Don't Mind
Contact by email	Email address:	

You can return this form by using the details below:

Aimee McMullan, Trainee Clinical Psychologist

Email: a.mcmullan@lancaster.ac.uk

Thank-you

Lancaster University

Appendix G: Consent forms

Lancaster University

Consent Form

Study Title: Exploring the feasibility and acceptability of online imagery focused techniques for people with psychosis

We are asking if you would like to take part in a research project that aims to assess how possible and acceptable an online intervention is for people with psychosis in the community, who experience mental images and persecutory delusions.
Before you consent to participating in the study, we ask that you read the participant information sheet. Consent will be taken by the trainee clinical psychologist reading each statement to you and asking if you agree, this verbal consent will be recorded. If you have any questions or queries before consenting please speak to the trainee clinical psychologist, Aimee McMullan.

Statements of consent	Please tick each box separately
1. I confirm that I have read the information sheet and fully understand what is expected of me within this study	
2. I confirm that I have had the opportunity to ask any questions and to have them answered	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected	
4. I understand that the researcher will discuss data with their supervisor as needed	
5. I understand that any information I give will remain confidential and anonymous unless it is thought that there is a risk of harm to myself or others, in which case the principal investigator will need to share this information with their research supervisor	
6. I consent to Lancaster University keeping completed data from the intervention for 10 years after the study has finished	
7. I consent to take part in the above study	
8. I agree to my GP being informed of my participation	
9. I consent to having my webcam turned on, where possible, throughout baseline and intervention sessions	

10. I would like to receive a written summary of the overall findings from the study	
11. In some circumstances, if you were to lose your capacity to consent or to take part in the study we would not expect or ask you to continue and ensure your GP knew to support you. If this was to happen, we would like to ask your permission now to keep your data from earlier visits and sessions (e.g. questionnaire responses,) to use in our research analysis	
12. I consent for recording of assessment sessions and therapeutic sessions for the trainee clinical psychologist's supervision purposes and to ensure model fidelity	

Name of Participant: _____ **Signature:** _____ **Date:** _____

Name of Researcher: _____ **Signature:** _____ **Date:** ____

Appendix H: Psychotic Symptom Rating Scale : PSYRATS ; Haddock et al 1999

A: Auditory Hallucinations	Amount of negative content of voices **Do your voices say unpleasant or negative things? Can you give me some examples of what voices say?** 0 No unpleasant content 1 Occasional unpleasant content (<10 %) 2 Minority of voice content is unpleasant or negative (<50 %) 3 Majority of voice content is unpleasant or negative (>50%) 4 All of voice content is unpleasant or negative
Frequency **How often do you experience voices?** 0.Voices not present or present less than once a week 1.Voices occur for at least once a week 2.Voices occur at least once a day 3.Voices occur at least once a hour 4.Voices occur continuously or almost continuously i.e. stop for only a few seconds or minutes	Degree of Negative Content 0 Not unpleasant or negative 1 Some degree of negative content, but not personal comments relating to self or family e.g. swearwords 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
Duration **When you hear voices, how long do they last?** 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	Amount of Distress **Are your voices distressing? How much of the time?** 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
Location **When you hear your voices where do they sound like they're coming from? Is it inside of your head and/or outside?** 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	Intensity of Distress **When voices are distressing, how distressing are they? Do they cause you minimal, moderate, severe distress?** 0 Voices not distressing at all 1 Voices slightly distressing 2 Voices are distressing to a moderate degree 3Voices are very distressing, although subject could feel worse 4 Voices are extremely distressing, feel the worst he/she could possibly feel
Loudness **How loud are your voices? Are they louder than your voice?** 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	Disruption to life caused by voices **How much disruption do the voices cause to your life? Do they prevent you from working or carrying out a daytime activity? Do they interfere with your relationships with family/friends? Do they interfere with your ability to look after yourself?** 0 No disruption to life, able to maintain social and family relationships (if present) 1 Voices causes 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 patient 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 patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient 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 hospitalization. The patient is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.
Beliefs re-origin of voices **What do you think has caused your voices? Are the voices caused by factors related to yourself or solely due to other people/factors?** **If external: How much do you believe that your voices are caused by X on a scale from 0-100, with 100 being that you are totally convinced, and 0 being completely untrue.** 0 Voices not present 1 Believes voices to be solely internally generated and related to self 2 Holds <50 % conviction that voices originate from external causes 3 Holds >50 % conviction (but <100 %) that voices originate from external causes 4 Believes voices are solely due to external causes (100% conviction)	Controllability of voice **Do you think you have any control over when your voices happen? Can you dismiss or bring on voices?** 0 Subject believes they can have control over the voices and can always bring on or dismiss them at will 1 Subject believes they can have some control over the voices on the majority of occasions 2 Subject believes they can have some control over their voices approximately half of the time 3 Subject believes they can have some control over their voices but only occasionally. The majority of the time the subject experiences voices which are uncontrollable 4 Subject has no control over when the voices occur and cannot dismiss or bring them on at all
B: Delusions	
Amount of preoccupation with delusions 0. No delusions, or delusions which the subject thinks about less than once a week 1. Subject thinks about beliefs at least once a week 2. Subject thinks about beliefs at least once a day 3. Subject thinks about beliefs at least once an hour 4. Subject thinks about delusions continuously oral most continuously	Amount of distress 0 Beliefs never cause distress 1 Beliefs cause distress on the minority of occasions 2 Beliefs cause distress on <50 % of occasions 3 Beliefs cause distress on the majority of occasions when they occur between 50-99% of time 4 Beliefs always cause distress when they occur
Duration of preoccupation with delusions 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 1 hour 4 Thoughts about delusions usually last for hours at a time	Intensity of distress 0 No distress 1 Beliefs cause slight distress 2 Beliefs cause moderate distress 3 Beliefs cause marked distress 4 Beliefs cause extreme distress, could not be worse
Conviction 0 No conviction at all 1 Very little conviction in reality of beliefs, <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%	Disruption to life caused by beliefs 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 patient 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 patient is able to maintain some daily activities, self-care and relationships while in hospital. The patient may be 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 hospitalization. The patient is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted

Appendix I: Calgary Depression Scale for Schizophrenia

Interviewer: Ask the first question as written. Use follow up probes or qualifiers at your discretion. Time frame refers to last two weeks unless stipulated. N.B. The last item, #9, is based on observations of the entire interview.

1. DEPRESSION: How would you describe your mood over the last two weeks? Do you keep reasonably cheerful or have you been very depressed or low spirited recently? In the last two weeks how often have you (own words) every day? All day? 0. Absent 1. Mild - Expresses some sadness or discouragement on questioning. 2. Moderate Distinct - depressed mood persisting up to half the time over last 2 weeks: present daily. 3. Severe - Markedly depressed mood persisting daily over half the time interfering with normal motor and social functioning	6. MORNING DEPRESSION: When you have felt depressed over the last 2 weeks have you noticed the depression being worse at any particular time of day? 0. Absent - No depression. 1. Mild Depression present but no diurnal variation. 2. Moderate Depression spontaneously mentioned to be worse in a.m. 3. Severe Depression markedly worse in am., with impaired functioning which improves in pm
2. HOPELESSNESS: How do you see the future for yourself? Can you see any future? - or has life seemed quite hopeless? Have you given up or does there still seem some reason for trying? 0. Absent 1. Mild - Has at times felt hopeless over the last two weeks but still has some degree of hope for the future. 2. Moderate - Persistent, moderate sense of hopelessness over last week. Can be persuaded to acknowledge possibility of things being better. 3. Severe - Persisting and distressing sense of hopelessness	7. EARLY WAKENING: Do you wake earlier in the morning than is normal for you? How many times a week does this happen? 0. Absent - No early wakening. 1. Mild - Occasionally wakes (up to twice weekly) 1 hour or more before normal time to wake or alarm time. 2. Moderate - Often wakes early (up to 5 times weekly) 1 hour or more before normal time to wake or alarm. 3. Severe - Daily wakes 1 hour or more before normal time
3. SELF DEPRECIATION: What is your opinion of yourself compared to other people? Do you feel better, not as good, or about the same as others? Do you feel inferior or even worthless? 0. Absent 1. Mild - Some inferiority; not amounting to feeling of worthlessness. 2. Moderate - Subject feels worthless, but less than 50% of the time. 3. Severe Subject feels worthless more than 50% of the time. May be challenged to acknowledge otherwise	8. SUICIDE: Have you felt that life wasn't worth living? Did you ever feel like ending it all? What did you think you might do? Did you actually try? 0. Absent 1. Mild Frequent thoughts of being better off dead, or occasional thoughts of suicide. 2. Moderate Deliberately considered suicide with a plan, but made no attempt. 3. Severe Suicidal attempt apparently designed to end in death (i.e.: accidental discovery or inefficient means).
.4. GUILTY IDEAS OF REFERENCE: Do you have the feeling that you are being blamed for something or even wrongly accused? What about? (Do not include justifiable blame or accusation. Exclude delusions of guilt.) 0. Absent 1. Mild Subject feels blamed but not accused less than 50% of the time. 2. Moderate Persisting sense of being blamed, and/or occasional sense of being accused. 3. Severe Persistent sense of being accused. When challenged, acknowledges that it is not so	9. OBSERVED DEPRESSION: Based on interviewer's observations during the entire interview. The question "Do you feel like crying?" used at appropriate points in the interview, may elicit information useful to this observation. 0. Absent 1. Mild Subject appears sad and mournful even during parts of the interview, involving affectively neutral discussion. 2. Moderate Subject appears sad and mournful throughout the interview, with gloomy monotonous voice and is tearful or close to tears at times. 3. Severe Subject chokes on distressing topics, frequently sighs deeply and cries openly, or is persistently in a state of frozen misery if examiner is sure that this is present
5. PATHOLOGICAL GUILT: Do you tend to blame yourself for little things you may have done in the past? Do you think that you deserve to be so concerned about this? 0. Absent 1. Mild Subject sometimes feels over guilty about some minor peccadillo, but less than 50% of time. 2. Moderate Subject usually (over 50% of time) feels guilty about past actions the significance of which he exaggerates. 3. Severe Subject usually feels s/he is to blame for everything that has gone wrong, even when not his/her fault	

Appendix J: Spontaneous Use of Imagery Scale

Participant ID: Date:

Please read each of the following descriptions and indicate the degree to which each is appropriate for you.

Do not spend a lot of time thinking about each one, but respond based on your thoughts about how you do or do not perform each activity.

If a description is always completely appropriate, please write "5"; if it is never appropriate, write "1"; if it is appropriate about half of the time, write "3"; and use the other numbers accordingly.

1. When going to a new place, I prefer directions that include detailed descriptions of landmarks (such as the size, shape and colour of a gas station) in addition to their names _____

2. If I catch a glance of a car that is partially hidden behind bushes, I automatically "complete it," seeing the entire car in my mind's eye _____

3. If I am looking for new furniture in a store, I always visualize what the furniture would look like in particular places in my home _____

4. I prefer to read novels that lead me easily to visualize where the characters are and what they are doing instead of novels that are difficult to visualize

5. When I think about visiting a relative, I almost always have a clear mental picture of him or her _____

6. When relatively easy technical material is described clearly in a text, I find illustrations distracting because they interfere with my ability to visualize the material. _____

7. If someone were to tell me two-digit numbers to add (e.g., 24 and 31), I would visualize them in order to add them _____

8. Before I get dressed to go out, I first visualize what I will look like if I wear different combinations of clothes _____

9.When I think about a series of errands I must do, I visualize the stores I will visit _____

10. When I first hear a friend's voice, a visual image of him or her almost always springs to mind _____

11. When I hear a radio announcer or DJ I've never actually seen, I usually find myself picturing what they might look like _____

12. If I saw a car accident, I would visualize what had happened when later trying to recall the details _____

Appendix K: Brief Core Schema Scale

This questionnaire lists beliefs that people can hold about themselves and other people. Please indicate whether you hold each belief (NO or YES). If you hold the belief then please indicate how strongly you hold it by circling a number (1-4). Try to judge the beliefs on how you have generally, over time, viewed yourself and others. Do not spend too long on each belief. There are no right or wrong answers and the first response to each belief is often the most accurate.

			Believe it slightly	Believe it moderately	Believe it very much	Believe it totally
Myself						
I am unloved	No	Yes	1	2	3	4
I am worthless	No	Yes	1	2	3	4
I am weak	No	Yes	1	2	3	4
I am vulnerable	No	Yes	1	2	3	4
I am bad	No	Yes	1	2	3	4
I am a failure	No	Yes	1	2	3	4
I am respected	No	Yes	1	2	3	4
I am valuable	No	Yes	1	2	3	4
I am talented	No	Yes	1	2	3	4
I am successful	No	Yes	1	2	3	4
I am good	No	Yes	1	2	3	4
I am interesting	No	Yes	1	2	3	4
Other People						
Other people are hostile	No	Yes	1	2	3	4
Other people are harsh	No	Yes	1	2	3	4
Other people are unforgiving	No	Yes	1	2	3	4
Other people are bad	No	Yes	1	2	3	4
Other people are devious	No	Yes	1	2	3	4
Other people are nasty	No	Yes	1	2	3	4
Other people are fair	No	Yes	1	2	3	4
Other people are good	No	Yes	1	2	3	4
Other people are trustworthy	No	Yes	1	2	3	4
Other people are accepting	No	Yes	1	2	3	4
Other people are supportive	No	Yes	1	2	3	4
Other people are truthful	No	Yes	1	2	3	4

Appendix L: Working Alliance Inventory – Short Revised

Instructions: Below is a list of statements and questions about experiences people might have with their therapy or therapist. Some items refer directly to your therapist with an underlined space -- as you read the sentences, mentally insert the name of your therapist in place of _____ in the text. Think about your experience in therapy, and decide which category best describes your own experience.

IMPORTANT!!! Please take your time to consider each question carefully.

1. As a result of these sessions I am clearer as to how I might be able to change.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

2. What I am doing in therapy gives me new ways of looking at my problem.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

3. I believe ___likes me.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

4. ___and I collaborate on setting goals for my therapy.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

5. ___and I respect each other.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

6. ___and I are working towards mutually agreed upon goals.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

7. I feel that ___appreciates me.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

8. _____ and I agree on what is important for me to work on.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

9. I feel _____ cares about me even when I do things that he/she does not approve of.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

10. I feel that the things I do in therapy will help me to accomplish the changes that I want.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

11. _____ and I have established a good understanding of the kind of changes that would be good for me.

⑤	④	③	②	①
Always	Very Often	Fairly Often	Sometimes	Seldom

12. I believe the way we are working with my problem is correct.

①	②	③	④	⑤
Seldom	Sometimes	Fairly Often	Very Often	Always

Appendix M: Adverse Effects of Psychotherapy

Learning from you: **Understanding your experience of an online imagery intervention**

Study ID: _____ **Date: _____**

Thank you for taking part in the online iMAPS case series study. We hope the results of our research will help us better understand the helpful and less helpful aspects of delivering iMAPS therapy online for psychosis. We would like to know a little bit more about your experience of the case series, and whether taking part causes you any distress. This will help us improve the way we do things in the future. Please not you do **not** have to tell us this. You do not have to complete this form if you do not want to.

If you could take the time to complete this questionnaire, we would be very grateful:

Please indicate the extent to which you agree with following statements:	Not at all	Very Little	A Little	Quite a Lot	Very Much
Taking part hasn't helped me with my problems.					
Taking part made my problems worse.					
Taking part made me feel more anxious.					
Taking part took up too much time.					
Taking part led to my mood becoming very low.					
Taking part made me feel more angry and irritable.					
I didn't feel ready to talk about my problems.					
Taking part made me think too much about bad things that have happened in the past.					
Taking part meant I stopped looking after myself properly.					
Taking part made me feel more suspicious.					
Taking part required too much energy or motivation.					
Taking part increased my thoughts of killing myself.					
Taking part made my voices or visions worse.					
Taking part was making me fall out with my family or friends.					

Please indicate the extent to which you agree with following statements:	NOT AT ALL	VERY LITTLE	A LITTLE	QUITE A LOT	VERY MUCH
Taking part was having a bad effect on my self-esteem.					
Taking part was making me want to harm myself.					
I felt embarrassed talking about my problems with people I had not met before.					
Taking part made me have thoughts of harming other people.					
Taking part was making me feel hopeless about the future.					
Taking part meant I had to increase my medication in order to cope.					
Taking part involved too much hard work.					
Taking part made me worry that people would think badly of me because of my diagnosis.					
Taking part made me fall out with my doctor or care team.					
Taking part made me worry about losing control of my mind.					
My problems have improved to the point whereby I no longer feel I need help.					

If you would like to describe your experience of taking part in this research in your own words, please use the following space:

_____

_____

_____

_____

Many thanks for your help and participation

Appendix N: Demographics

Participant number	
Gender	Male ☐ Female ☐
Date of birth (dd/mm/yyyy)	/ /
Age (years)	
Highest level of education	Primary School ☐ Secondary School ☐ Further Education (e.g. College) ☐ Higher Education (e.g. University) ☐
Employment status	Full Time ☐ Part Time ☐ Retired ☐ Voluntary ☐ Student ☐ Home duties ☐ Unemployed ☐
Marital status	Single ☐ Married ☐ Living with partner ☐ Civil Partnership ☐ Separated ☐ Divorced ☐ Widowed ☐
Living arrangements (Who does the person live with?)	Spouse/Partner only ☐ Spouse/Partner plus children ☐ Spouse/Partner plus other/s (not children) ☐ Alone ☐ Children only ☐ Parent/s only ☐ Friend/s only ☐ Supported accommodation/hostel ☐ Other ☐ Specify _____

Ethnic origin (ask as an open question and record)

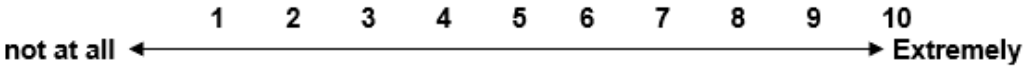
Asian or Asian British ☐ Bangladeshi ☐ Indian ☐ Pakistani ☐ Any other Asian background **Black or Black British** ☐ African ☐ Caribbean ☐ Any other Black background	**Mixed** ☐ White & Asian ☐ White & Black African ☐ White & Black Caribbean ☐ Any other mixed background **White** ☐ British ☐ Irish ☐ Any other White background	**Other Ethnic Group** ☐ Chinese ☐ Any other ethnic group Specify _____

Appendix O: Mental Imagery in Psychosis Questionnaire

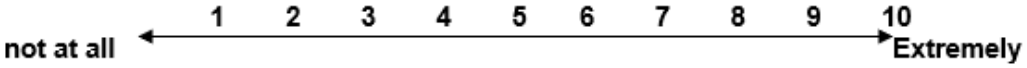
Mental Imagery in Psychosis Questionnaire

Please rate how your images have been over the past week

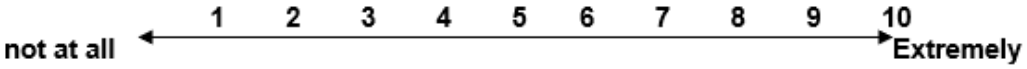
1. How compelling was the image?



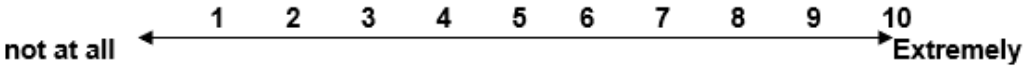
2. How real was the image?*



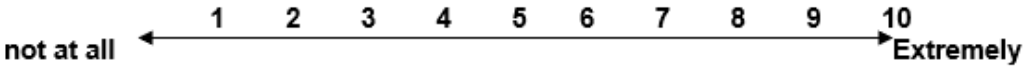
3. How vivid was the image?



4. How absorbing was the image?



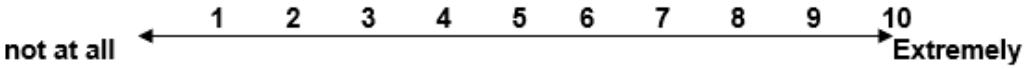
5. How preoccupying was the image?



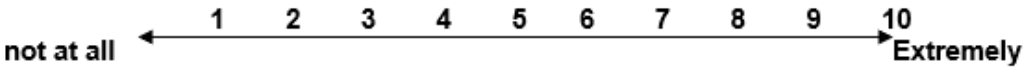
- *Please see manuscript for details of discussing "how real" an image is with someone experiencing psychosis.*
- *We thank Professor Emily Holmes, Karolinska Institutet and University of Cambridge for sharing an earlier imagery characteristics Visual Analogue Scale (VAS).*

Additional Questions

To which extent could you understand the role that the image play in changing your mood?



To which extent could you find positive / helpful ways of using the image?



Appendix P: Sessional Mood Rating

“How would you rate your mood today, with 0 being the worst it has ever been and 10 being the best?”

Appendix Q: Positive and Negative Syndrome Scale, PANSS Positive Subscale

P1 Delusions

RECORD NUMBER OF DELUSIONS WITH EXAMPLES

- **Delusions of interference with thinking:** Can you think clearly or is there interference with your thoughts? What kind of interference?
- **Delusions of thought insertion:** Are you in full control of your thoughts? Are thoughts put into your head which you know are not your own? How do you know they are not your own? Where do they come from?
- **Delusions of thought broadcast:** Do you ever seem to hear your own thoughts spoken aloud in your head, so that someone standing near might be able to hear them? How do you explain this? Are your thoughts broadcast so that other people know what you are thinking?
- **Delusions of thought echo or commentary:** Do you ever seem to hear your own thoughts repeated or echoed? What is that like? How do you explain it? Where does it come from?
- **Delusions of thought block:** Do you ever experience your thoughts stopping quite suddenly so that there are none left in your mind, even though your thoughts were flowing freely before? What is that like? How does it occur? What is it due to?
- **Delusions of thought withdrawal:** Do your thoughts ever seem to be taken out of your head, as though some external person or force were removing them? Can you give an example? How do you explain it?
- **Delusions of thoughts being read:** Can anyone read your thoughts? How do you know? How do you explain it?
- **Delusions of control:** Do you ever feel under the control of some force of power other than yourself? As though you were a robot without a will of your own? As though you were possessed by someone or something else? What is that like?
- **Delusions of reference:** Do you find that complete strangers sometimes talk about you? What do they say? Do people seem to drop hints about you, or say things with a double meaning, or do things in a special way so as to convey a meaning? Can you give an example of what they say/do? Is there any reference to you in the newspapers or television? Do you see any special meaning for yourself in the colours of objects or the way things are arranged?
- **Delusional misinterpretation or misidentification:** Are there people around who are not what they seem to be? Do you ever feel that the place you are in is not what it seems to be? Is anyone keeping a special watch on you? Do you feel you are being tested out in some way?
- **Delusions of persecution:** Is anyone deliberately trying to harm you, e.g. trying to poison you or kill you? How? Is there any kind of organisation behind it? Is there any other kind of persecution?
- **Assistance:** Do you think people are organising things specially to help you? What are they doing?
- **Grandiose abilities**: Is there anything special about you? Do you have any special powers or abilities? Can you read people's thoughts? Is there a special purpose or mission to your life? Are you especially clever or inventive?
- **Grandiose identity**: Are you a very prominent person or related to someone prominent like royalty? Are you very rich or famous? How do you explain this?
- **Religious delusions**: Are you a very religious person? Specially close to God? Can God communicate with you? Are you yourself a saint?
- **Delusional explanations**: How do you explain the things that have been happening? Is anything like hypnotism or telepathy going on? Is anything like electricity or X-rays or radio waves affecting you?
- Do you think your appearance is normal?

P1 Delusions

Beliefs which are unfounded, unrealistic, and idiosyncratic.

Basis for rating: Thought content expressed in the interview on social relations and behaviour.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – Presence of one or two delusions which are vague, uncrystallized, and not tenaciously held. Delusions do not interfere with thinking, social relations, or behaviour.
4. Moderate – Presence of either a kaleidoscopic array of poorly formed, unstable delusions or of a few well-formed delusions that occasionally interfere with thinking, social relations, or behaviour.
5. Moderate-Severe – Presence of well-formed delusions that are tenaciously held and occasionally interfere with think, social relations, and behaviour.
6. Severe – Presence of a stable set of delusions which are crystallized, possibly systematised, tenaciously held, and clearly interfere with thinking, social relations, and behaviour.
7. Extreme – Presence of a stable set of delusions which are either highly systematised or very numerous, and which dominate major facets of the patient's life. This frequently results in inappropriate and irresponsible action, which may even jeopardise the safety of the patient or others.

P2 Conceptual Disorganisation

OBSERVATION

Does the patient reply to questions in an irrelevant manner?

Does the patient show a pattern of speech in which his/her ideas slip off the tract onto another one which is indirectly related or completely unrelated? Does the patient show a pattern of speech in which conclusions are reached which do not seem to follow logically?

Do the patient's replied last for ages so that they have to be interrupted and urged to get to the point?

Can the patient focus his/her thoughts on the question?

P2 Conceptual disorganisation

Disorganised process of thinking characterised by disruption of goal directed sequencing, e.g. circumstantially, tangentially, loose associations, nonsequiturs, gross illogicality, or thought block.

Basis for rating: Cognitive-verbal processes observed during the course of the interview.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – Thinking is circumstantial, tangential, or paralogical. There is some difficulty in directing thoughts towards a goal, and some loosening of associations may be evidenced under pressure.
4. Moderate – Able to focus thoughts when communications are brief and structured, but becomes loose or irrelevant when dealing with more complex communications or when under minimal pressure.
5. Moderate-Severe – Generally has difficulties in organising thoughts, as evidenced by frequent irrelevancies, disconnectedness, or loosening of association even when not under pressure.
6. Severe – Thinking is seriously derailed and internally inconsistent, resulting in gross irrelevancies and disruption of thought processes, which occur almost constantly.
7. Extreme – Thoughts are disrupted to the point where the patient is incoherent. There is marked loosening of associations, which result in total failure of communication, e.g. "word salad" or mutism.

P3 Hallucinatory behaviour

- **Do you ever seem to hear noises or voices when there is no one about and nothing else to explain it?** *(auditory hallucinations)*
- **Do you sometimes hear noises like tapping or music? Do you hear muttering or whispering?** *(nonverbal auditory hallucinations)* What are these like? How often have you heard them during the last week? Do they bother you? What do you think is the cause of the noise/s
- **Do you ever hear a voice talking?** *(verbal auditory hallucinations)*

If yes:

- **Have you heard voices in the last 7 days?**
- **How many voices have you heard in the last week?**

RECORD THE FOLLOWING FOR EACH VOICE:

- **Do the voices speak directly to you?** *(second person auditory hallucinations*) **Or do they refer to you as 'he' or 'she?'** *(Third person auditory hallucinations).*
- **Are the voices a man or a woman's voice?**

PANSS hallucinations in other modalities

- **Have you had any unusual visual experiences recently? *(visual hallucinations).***
- Was this in the last week? How often in the last week?
- What did you see? **RECORD NUMBER OF HALLUCNATIONS AND WHAT WAS SEEN**

- How real does this appear? As real as I do now? Was it in colour? Was it 3 dimensional or flat? Did you see it with your eyes or in your mind? Did other people see it? When you saw it were you falling asleep or waking up at the time?
- What do you think caused the vision/s? Factors relating to you or other people? On a scale of 0 to 100 how convinced are you that.....caused the vision/s? **RECORD FOR EACH VISION**
- **Do you sometimes notice strange smells that other people don't notice? *(olfactory hallucinations).***
- Was this in the last week? How often in the last week?
- What sort of thing do you smell? How do you explain it? **RECORD NUMBER AND WHAT WAS SMELT**
- What do you think caused the smell/s? Factors relating to you or other people? On a scale of 0 to 100 how convinced are you that.....caused the smell/s? **RECORD ORIGIN FOR EACH SMELL**
- **Do you ever feel that someone is touching you, but when you look there is nobody there? *(tactile hallucinations)***
- Was this in the last week? How often in the last week?
- What sort of thing do you feel? How do you explain it? **RECORD NUMBER AND WHAT WAS FELT**
- What do you think caused the feeling/s? Factors relating to you or other people? On a scale of 0 to 100 how convinced are you that.....caused the feeling/s? **RECORD ORIGIN FOR EACH FEELING**
- **Do you sometimes get strange feelings in your body? *(somatic hallucinations)***
- Was this in the last week? How often in the last week?
- What sort of thing do you feel? How do you explain it? **RECORD NUMBER AND WHAT WAS FELT**
- What do you think caused the feeling/s? Factors relating to you or other people? On a scale of 0 to 100 how convinced are you that.....caused the feeling/s? **RECORD ORIGIN FOR EACH FEELING**
- **Do you ever find that your food tastes unusual? *(gustatory hallucinations)*.**
- Was this in the last week? How often in the last week?
- What sort of thing do you taste? How do you explain it? **RECORD NUMBER AND WHAT WAS TASTED**
- What do you think caused the taste/s? Factors relating to you or other people? On a scale of 0 to 100 how convinced are you that.....caused the taste/s? **RECORD ORIGIN FOR EACH TASTE**

P3 Hallucinatory Behaviour

Verbal report or behaviour indicating perceptions which are not generated by external stimuli. These may occur in the auditory, visual, olfactory, or somatic realms.

Basis for rating: Verbal report and physical manifestations during the course of the interview as well as reports of behaviour by primary care workers of family.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – One or two clearly formed but infrequent hallucinations, or else a number of vaque abnormal perceptions which do not result in distortions of thinking or behaviour.
4. Moderate – Hallucinations occur frequently but not continuously, and the patient's thinking and behaviour are affected only to a minor extent.
5. Moderate-Severe – Hallucinations are frequent, may involve more than one sensory modality, and tend to distort thinking and/or disrupt behaviour. Patient may have a delusional interpretation of these experiences and respond to them emotionally and, on occasion, verbally as well.
6. Severe – Hallucinations are present almost continuously, causing major disruption or thinking and behaviour. Patient treats these as real perceptions, and functioning is impeded by frequent emotional and verbal responses to them.
7. Extreme – Patient is almost totally preoccupied with hallucinations, which virtually dominate thinking and behaviour. Hallucinations are provided a rigid delusional interpretation and provoke verbal and behavioural responses, including obedience to command hallucinations.

P4 Excitement

OBSERVATION

Can the patient sit still?

Does the patient get over excited or restless?

P4 Excitement

Hyperactivity as reflected in accelerated motor behaviour, heightened responsivity to stimuli, hypervigilance, or excessive mood lability.

Basis for rating: Behaviour manifestations as well as reports of behaviour by primary care workers or family.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – Tends to be slightly agitated, hypervigilant, or mildly over-aroused throughout the interview, but without distinct episodes of excitement or marked mood lability. Speech may be slightly pressured.
4. Moderate – Agitation or over-arousal is clearly evident throughout the interview, affecting speech and general mobility, or episodic outbursts occur sporadically.
5. Moderate-Severe – Significant hyperactivity or frequent outbursts of motor activity are observed, making it difficult for the patient to sit still for longer than several minutes at any given time.

6. Severe – Marked excitement dominates the interview, delimits attention, and to some extent affects personal functions such as eating and sleeping.
7. Extreme – Marked excitement seriously interferes in eating and sleeping and makes interpersonal interactions virtually impossible. Acceleration of speech and motor activity may result in incoherence and exhaustion.

P5 Grandiosity

- Do you think you are special in some way?
- What are your good points?
- Have you had any thoughts recently about having special powers, talents or abilities, or being more important than other people?

If yes

- What are your special powers/talents/abilities? (*Wealth, knowledge, fame, moral righteousness)*
- How often have you thought about this in the past week? Most days? How much of the time?
- Are you certain that you have this special power/talent/ability? 100% certain?
- How do these abilities affect your day to day life?
- Could you be mistaken? Is there any other possible explanation?

P5 Grandiosity

Exaggerated self-opinion and unrealistic convictions or superiority, including delusions of extraordinary abilities, wealth, knowledge, fame, power, and moral righteousness.

Basis for rating: Thought content expressed in the interview and its influence on behaviour.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – Some expansiveness or boastfulness ids evident, but without clear-cut grandiose delusions.
4. Moderate – Feels distinctly and unrealistically superior to others. Some poorly formed delusions about special status or abilities may be present but are not acted upon.
5. Moderate-Severe – Clear-cut delusions concerning remarkable abilities, status, or power are expressed and influence attitude but not behaviour.
6. Severe – Clear-cut delusions or remarkable superiority involving more than one parameter (wealth, knowledge, fame, etc.) are expressed, notably influence interactions, and may be acted upon.
7. Extreme – Thinking, interactions, and behaviour are dominated by multiple delusions of amazing ability, wealth, knowledge, fame, and/or moral stature, which may take on a bizarre quality.

P6 Suspiciousness/Persecution

- Have you felt uneasy or suspicious about anything in the past week?
- Do you generally get on okay with other people?
- Do you trust most people that you know? Are there any people you distrust? Who? Why do you think that is?
- Do people sometimes talk about you behind your back/ spy on you/watch you? What do they say? Why?
- Are people out to harm you?

If yes:

- What is the evidence for all this? Who is behind all this? Why does this happen?
- Do your feelings abut others affect the way you talk to people? Does it make you not want to talk to people?

P6 Suspiciousness/persecution

Unrealistic or exaggerated ideas of persecution, as reflected in guardedness, a distrustful attitude, suspicious hypervigilance, or frank delusions that others mean one harm.

Basis for rating: Thought content expressed in the interview and its influence on behaviour.

1. Absent – Definition does not apply.
2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.
3. Mild – Presents a guarded or even openly distrustful attitude, but thoughts, int6eractions, and behaviour are minimally affected.
4. Moderate – Distrustfulness is clearly evident and intrudes on the interview and/or behaviour, but there is no evidence of persecutory delusions. Alternatively, there may be indication of persecutory delusions, but these do not seem to affect the patient's attitude or interpersonal relations.
5. Moderate-Severe – Patient shows marked distrustfulness, leading to major disruption of interpersonal relations, or else there are clear-cut persecutory delusions that have limited impact on interpersonal relations and behaviour.
6. Severe – Clear-cut pervasive delusions or persecution which may be systematised and significantly interfere in interpersonal relations.
7. Extreme – A network systematised persecutory delusions dominate the patient's thinking, social relations, and behaviour.

P7 Hostility

OBSERVATION

Is the patient sarcastic / irritable / verbally abusive / violent?

P7 Hostility

Verbal and non-verbal expressions of anger and resentment, including sarcasm, passive-aggressive behaviour, verbal abuse, and assaultiveness.

Basis for rating: Interpersonal behaviour observed during the interview and reports by primary care workers and family.

1. Absent – Definition does not apply.

2. Minimal – Questionable pathology; may be at the upper extreme of normal limits.

3. Mild – Indirect or restrained communication of anger, such as sarcasm, disrespect, hostile expressions, and occasional irritability.

4. Moderate – Presents an overtly hostile attitude, showing frequent irritability and direct expression of anger or resentment.

5. Moderate-Severe – Patient is highly irritable and occasionally verbally abusive and threatening.

6. Severe – Uncooperativeness and verbal abuse or threats notably influence the interview and seriously impact upon social relations. Patient may be violent and destructive but is not physically assaultive toward others.

7. Extreme – Marked anger results in extreme uncooperativeness, precluding other interactions, or in episode(s) of physical assault toward others.

Appendix R: Helpline sheet

Let's Talk About Mental Health

If you are worried about your mental, then make an appointment with your GP. When people have physical health problems they go to their doctor for advice, help and treatment; it is exactly the same if you experience any mental health problems.

If you need help **urgently**, try one of the options below:

Samaritans – Confidential and emotional support for people with feelings of distress or any mental health problem.

Open 24 hours a day, 365 days a year

Call: 08457 90 90 90 or 116 123

Web: www.samaritans.org

Sane – Provides a service for you to speak about your mental health, or the mental health of anyone you care about.

Open 6pm – 11pm, 365 days a year.

Call: 0845 767 8000

Textcare: comfort and care via text message: www.sane.org.uk/textcare

Peer support forum: www.sane.org.uk/supportforum

Web: www.sane.org.uk.support

CALM - Campaign Against Living Miserably, for men aged 15 to 35

Open: 5pm to midnight, daily

Phone: 0800 58 58 58 5pm

Web: www.thecalmzone.net

Rethink Mental Illness - support and advice for people living with mental illness

Open: 09:30am to 4pm, Monday to Friday

Call: 0300 5000 927

Web: www.rethink.org

Appendix S: List of Resources

If you are interested in other research projects that you may be able to take part in:

Be Part of Research by National Institute for Health Research:
https://bepartofresearch.nihr.ac.uk/

More information about clinical trials can be found on the NHS website:

NHS Clinical Trials: www.nhs.uk/conditions/clinical-trials

Other resources:

Books

- Overcoming Paranoid and Suspicious Thoughts by Daniel Freeman
- Living Life to the Full: Key life skills to change your life, by Prof. Christopher Williams

Websites

- Paranoid Thoughts: - https://www.paranoidthoughts.com/
  - "all about unfounded or excessive fears about others. Such fears may be referred to as 'paranoid thoughts' or 'paranoia'
- Hearing Voices Network: http://www.hearing-voices.org/
  - Focus on helping to create respectful and empowering spaces, whilst challenging the inequalities and oppressive practices that hold people back
  - Free resources and information on website
- More information:
  - https://www.rethink.org/advice-and-information/about-mental-illness/learn-more-about-conditions/psychosis/
  - https://www.mind.org.uk/media-a/4293/psychosis-2020-pdf-download.pdf
  - https://nationalparanoianetwork.org/

Appendix T: Pre-Treatment Risk Assessment

Eligibility Screen	
Potential Participant ('P') ID number:	
Name of person completing form:	**Date of form completion:**

Inclusion criteria details:

Aged 18-65? Y/N

Diagnosis of psychosis, schizophrenia-spectrum disorder, schizoaffective disorder? Y/N

Experience persecutory delusions, paranoid beliefs or suspicious beliefs? Y/N

Exclusion criteria details;

Developmental disability (including autistic spectrum disorder)? Y/N

Non-English speaking? Y/N

Poses unmanageable risk of violence to researcher or clinician? Y/N

To be eligible, P must have N circled for all the above. <u>Remember,</u> further eligibility testing will also be required. Risk of harm to self or others must be assessed using the pre-visit risk assessment form overleaf.

Pre-Visit Risk Assessment

Potential Participant ('P') ID number:

Name of person completing form:	**Date of form completion:**
Nature of current contact with services: Inpatient ☐ Outpatient ☐ Other ☐ Specify:	**Previous contact with services (please specify):** _____ _____ _____

ENVIRONMENTAL RISK

Any environmental risk? Current ☐ Past ☐ Both ☐ None identified ☐

If current or past, provide details:

_____

_____

Risks with relatives / others? Yes ☐ No ☐ Don't know ☐ Not applicable ☐

If Yes, provide details:

_____

_____

Risks from animals? Yes ☐ No ☐ Don't know ☐ Not applicable ☐

If Yes, provide details:

_____

_____

RISK OF SUICIDE OR SELF-HARM

Any risk of self-harm? Current □ Past □ Both □ None identified □

If Current or Past, provide details:

_____

_____

_____

If P has had previous suicide attempts, please specify number of attempts if known, method, locality, extent of concealment, level of intent, preparation

_____

_____

_____

_____

If P has current suicidal ideation, please specify frequency, duration, level of intent, access to preferred means of suicide:

_____

_____

_____

_____

Any recent stressors for P (illness, break-up, bereavement)? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Does P have fears of mental disintegration Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Has P recently been discharged from inpatient psychiatric care? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Does P engage in current alcohol and/or drug misuse? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Level of risk of suicide as judged by referrer: Low □ Moderate □ High □ Very High □

Referrer's rationale for rating:

_____

_____

_____

_____

_____

RISK OF HARM TO OTHERS

Any known risk of harm to others? Current □ Past □ Both □ None identified □

If Current or Past, provide details:

_____

_____

_____

Any risk of harm to children? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any risk of harm of sexual assault? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any incidents involving police Yes □ No □ Don't know □

If Yes, provide details (number, nature of incidents):

_____

_____

Any threats / thoughts / hallucinations / delusions

which indicate potential harm to others? Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

Any previous convictions for violent crime Yes □ No □ Don't know □

If Yes, provide details (including whether planned or impulsive and whether weapons involved):

_____

_____

Diagnosis of antisocial personality disorder and/or presence of psychopathic personality traits?

Yes □ No □ Don't know □

If Yes, provide details:

_____

_____

After consulting with P, describe P's risk management plan below::

(i.e., Is there a crisis management plan for P?; Who are the contacts in a crisis? Identify friend, family, caregiver, crisis teams who could be made aware of P's participation in the study. If there are any safeguarding issues disclosed by P during the study, what is the action plan?)

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Do CI and RA agree that risk is manageable within the bounds of the study protocol?

Y/N

If N, then P is not eligible to participate.

Appendix U: Capacity

Our definition of capacity is based on the Mental Capacity Act Legislation (2005). The Code of Practice for the Mental Capacity Act (Department for Constitutional Affairs; DCA, 2007) recommends a two-stage model for assessing capacity that combines a status and a functional approach (p.41).

The person to be assessed must have:

i) an impairment of or disturbance in functioning of the mind or brain (temporary or permanent) and this must have

ii) made the person unable to make a particular decision at the time it needs to be made. Capacity is presumed until proven otherwise, although it is recognised to fluctuate (p.49, DCA, 2007).

The factors required to have capacity set out in the Code of Practice (DCA, 2007) are the abilities to:

1) understand the decision and why they need to make it

2) understand the information relevant to the decision; which would include consequences of the decision (benefits and risks) and alternatives to the proposed solution, including taking no action or making no decision

3) Retain the information; with the period of time required relating to the decision (for sufficiently long enough to make the decision, and with consistency across different time points if memory span is very short)

4) Use or weigh the information to make a decision; which would preclude people with addictions or impulsivity who may understand the consequences but not be able to abate their actions

5) Communicate their decision; which may include a simple yes/no answer or consistent non-verbal communication

Capacity can be assessed using a diagnostic approach, outcome approach or a functional approach.

As a Doctoral trainee clinical psychologist, with several years' experience of working in healthcare and research, the researcher has received training on the Mental Capacity Act in the form of several day long workshops as part of the clinical psychology doctorate curriculum. There have been opportunities to consider capacity while carrying a client caseload whilst working with children, adolescents and adults over the last 14 months.