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Investigation of attention training for people with psychosis

Submission date	Recruitment status	[X] Prospectively registered
23/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/08/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/03/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to run a trial of Attention Training Technique (ATT) compared to treatment as usual (TAU) for patients with psychosis to test its feasibility and acceptability. This allows the testing of key questions about recruitment and retention, provides a test of the protocol and will gather information about ATT including the training and supervision needs of those providing it. Information about acceptability and feasibility will be used to develop a large scale trial to test the effectiveness of ATT for psychosis.

Who can participate?
Patients aged 16 or over with psychosis

What does the study involve?
Participants are randomly allocated to one of two groups to receive either ATT plus TAU or TAU alone. The ATT intervention is delivered by a care coordinator over 12 sessions. All participants are assessed at the start of the study, 12 weeks, 6 months and 12 months. Participants' experiences of ATT and of being involved in the trial and staff/professionals views of the trial are also collected.

What are the possible benefits and risks of participating?
Participants that are randomly allocated to ATT plus TAU will have the benefit of receiving a low intensity intervention that has been found to have positive effects, without a lengthy waiting list. For participants who are not allocated to ATT, having regular assessments is considered a potential benefit given that it presents an enhancement from routine care as symptoms will be monitored more regularly and in a more comprehensive manner. Some participants may find completing some of the assessments distressing. In order to minimise this, participants will be offered choice regarding the length of the assessments, including the option of breaks and completing the assessments across multiple sessions. There is a standardised protocol for managing distress that has been developed with service users. The protocol includes providing a crisis card listing relevant phone numbers and offering standardised telephone contact within 48 hours of assessments. In addition, if a participant begins to show signs of distress during an assessment the researcher will discuss this with the participant, have a break or stop the assessment. With the participants consent the researcher will also liaise with the care

coordinator (e.g. they could attend the initial assessment to help the participant feel more comfortable, or if the participant wishes the researcher to do so they can inform the care coordinator of the distress reported). Furthermore, the researcher will gain advice from their supervisor and take any appropriate action to minimise the participant's distress. The participant will be able to freely withdraw from the study at any point, which will also be clear on the consent form and this will not affect their statutory care.

Where is the study run from?
Community Mental Health Teams within Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2018 to June 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Sophie Parker
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
37690

Study information

Scientific Title

A randomised controlled trial investigating Attention Training Technique in psychosis: a feasibility study

Acronym
iATTp

Study objectives
The aim of this study is to run a randomised controlled trial (RCT) of Attention Training Technique (ATT) compared to treatment as usual (TAU) for individuals with psychosis to test its feasibility and acceptability. This allows the testing of key questions about recruitment and retention, provides a test of the protocol and will gather information about ATT including training and supervision needs of those providing it. Information about acceptability and feasibility will be used to develop an application for a definitive large scale trial to test the effectiveness of ATT for psychosis. This study will enable a robust definitive trial by giving information for sample size, treatment requirements (e.g. training and supervision) and a finalised protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester East Research Ethics Committee favourable opinion letter 23 /07/2018 (HRA approval pending), ref: 18/NW/0458

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychosis

Interventions
STUDY DESIGN
The study will be a single (rater) blind randomised feasibility study with two conditions; Attention Training Technique (ATT) plus treatment as usual (TAU) vs. TAU alone for people with psychosis. The trial will randomly allocate participants who meet criteria to a 12-week package of either condition. Assessors blind and independent to treatment group will conduct assessments at baseline, post-treatment (3 months) and follow-up (6 and 12 months).

The main trial will include a nested qualitative study that will identify key themes associated with the acceptability of ATT for people with psychosis and experiences of being involved in the trial as well as staff views.

SAMPLE SIZE
A sample size of 60 is considered adequate for obtaining reliable sample size estimates to facilitate the main aims of a feasibility study. Based on requiring 60 participants across conditions a target recruitment of 76 (38 per condition) over the recruitment period would allow a dropout rate of 20% although this is likely to be lower.

RECRUITMENT
Recruiting to target will rely on case-finding through services. The trial will be run from the Psychosis Research Unit (PRU) at Greater Manchester Mental Health NHS Foundation Trust where the CI is based. Potential participants will be identified via care-coordinators and relevant mental health staff in community mental health teams (CMHT). CMHT's will be made aware of the study via regular liaison from researchers. Participants may also identify themselves as suitable for the study via the Greater Manchester FAIR (Free Access to Involvement in Research) system or by contact numbers provided on press releases and posters.

RANDOMISATION
Following written consent and assessment, eligible participants will be randomised within 2 working days of eligibility being confirmed. Randomisation will be undertaken using Sealed Envelope software (https://www.sealedenvelope.com/). Randomisation (at the individual level) will be independent and concealed, using randomised-permuted blocks of 4-6 after stratification by gender and age. Randomisation will be coordinated by Professor Dunn, who is affiliated to the CRC-registered Manchester Academic Health Sciences Coordination Unit (MAHSC-CTU, UK. CRC Registration Number 9). Allocation is communicated to trial manager (to monitor adherence to the randomisation algorithm), trial therapists and made known to the participant by letter from the administrator.

Blinding of allocation will be maintained for research assistants until all outcome measures for all subjects have been collected. Blindness will be maintained using a range of measures (e.g. separate offices for therapist and researchers, protocols for answering phones, message taking and secretarial support, separate diaries and security for electronic randomisation information). Maintaining rater-blindness to treatment allocation is crucial, and the Trial Steering Committee (TSC) will regularly monitor unblindings, and implement corrective action if necessary.

TREATMENT ARM: ATTENTION TRAINING TECHNIQUE PLUS TAU
Those randomised to receive ATT plus TAU (n=38) will receive a maximum of 12 sessions delivered over twelve weeks (where day 0 is the day of allocation/randomisation). Attention Training Technique (ATT) is delivered via audio-recording and sessions are structured in line with ATT manuals. Participants will be assisted in developing their skills in selective attention, rapid attention, switching and divided attention. This is done using an auditory modality (CD, MP3), as research has shown this to have greater success than using visual tasks. ATT Participants will be asked to practice this as a home-task between sessions once per day for twelve minutes. Intervention will be on a 1:1 basis with a care-coordinator trained to deliver ATT, working under supervision from Wells and Parker. Each session lasts approximately 30 minutes consisting of an overview of the last week including practice issues, followed by the 12 minute auditory attention training task with facilitated learning (adherence checklist utilised). The administration of assessments to be taken at weekly intervals will occur outside of the session time.

Measures will be taken to record sessions offered and used across this time period to review adherence robustly through listening to tapes and rating session adherence. Offering 12, 30 minute sessions over the treatment window will still derive an intervention consisting of approximately 6 hours of face to face contact. This fits within the guidelines for what would be expected from a low-intensity intervention.

CONTROL CONDITION: TAU ALONE
The control condition (n=38) will receive TAU plus follow-up (3, 6 and 12 months), which represents an enhancement over routine care since this includes comprehensive and regular monitoring of mental state through the research assessments. We will not be asking referrers to withhold any treatment that forms part of TAU. Assessments will identify any risks to self or others that require immediate action. TAU will not include liaison with a clinical team except where risk issues necessitate this. This is a pragmatic approach that will improve generalisability of our findings. As in previous trials we have undertaken, there will be a clear safety protocol to alert clinicians should suicidal or dangerous ideation emerge. All routine or additional treatments in both conditions will be monitored using a Treatment Documentation Sheet. It is advised that individuals do not receive concomitant psychological therapy.

ASSESSMENTS
The baseline assessment will be performed by the research assistant and will take place at a venue chosen by the participant in line with the Psychosis Research Unit (PRU) policy, for example, home visit, CMHT, GP surgery or other community venue. The aim of the baseline assessment is to ensure each participant is checked for eligibility (including measurement of all inclusion and exclusion criteria) and to provide a baseline measurement prior to randomisation of all measures of outcome to be undertaken at subsequent visits (see below).

The assessments performed at the Baseline / Eligibility Assessment are: Participant Eligibility Form; PANSS; HADS; MCQ-30; CAS; ACS; SARS; QPR; AUDIT; DUDIT; WHOQOL; GAF; SOFAS; EPQ (adapted); EQ-5D; Health Service Receipt Inventory. Eligibility will be ascertained via discussion with the Chief Investigator of all inclusion and exclusion criteria information ascertained in the baseline visit and the Eligibility Form will be completed and signed off by the research assistant and chief investigator at this point.

All participants will be assessed at subsequent visits for follow-up at the following time points : 12 weeks, 6 months and 12 months. All visits will be performed by the research assistant and will take place at a venue chosen by the participant in line with the PRU policy, for example, home visit, CMHT, GP surgery or other community venue. All outcome measures will be performed at each of the follow-up assessments; PANSS; HADS; MCQ-30; CAS; ACS; SARS; QPR; AUDIT; DUDIT; WHOQOL; GAF; SOFAS; EPQ (adapted); EQ-5D; Health Service Receipt Inventory. Assessment information for each participant will be discussed with the Chief Investigator to finalise the scoring outcome for the PANSS assessment and the Follow-up Assessment Form completed and signed off at this point. An additional part of each follow-up assessment will include adverse event recording, assessing any risk if this arises and the provision of an up to date crisis card.

At the 12 month visit an additional questionnaire (iATTp Qualitative Topic Guide Questionnaire) will be administered to ask participants to comment on their unique personal experiences of being involved in the trial. The questionnaire, adapted from the topic guide used in the nested qualitative study, will only be given to participants who have not taken part in the qualitative study. As the qualitative interviews are only completed by a minority of participants and therefore may be a risk to self-selecting bias to those with most polarised views of the trial. This will provide all participants in the trial an opportunity to respond to these questions.

ADDITIONAL CONTACT:
In order to maximise the ongoing involvement and retention of participants a number of procedures for additional contact will be put in place. All procedures are in line with PRU policies leading to the successful running of research trials for people with psychosis and have been developed over a number of years with the Service User Reference Group (SURG) which operates

as a fundamental part of PRU. Additional contact will be provided by means of a planned telephone call at 9 months following randomisation and intermittent written contact via newsletters and cards.

The 9 month telephone contact will consist of asking about general wellbeing since the last assessment (including documenting any adverse events) any changes to contact details and we will offer a £5 voucher at this point to thank participants for their continued participation.

The intermittent contact via newsletter and cards will be provided only where participants give permission for their home or email address to be used for contact. Although the specific timings of these contacts are not pre-specified, this will not amount to more than 4 additional written contacts. Consent to send this information will be ascertained although it will be made clear to the participant that trial participation will not be contingent upon this.

EXPENSES
Participants will receive a £20 payment at the baseline appointment and at the end of each of the 3 follow-up visits and £5 for the phone call at 9 months (£85 in total). This will be offered since participating in the research study may require some effort and take up the participants' time. This payment will allow for reasonable travel expenses for any visits additional to normal care thereby increasing the opportunity of fair access to all service users for involvement in research.

QUALITATIVE STUDY
A nested qualitative approach will be employed to identify key themes associated with the acceptability of the overall study and ATT amongst participants. The interview, designed by a service-user with a wider user-group, will inform the design of a definitive trial, informing protocol changes or treatment adaptations.

Semi-structured interviews will be conducted with participants, after treatment (e.g. after 12 week follow-up), randomised to ATT and those who are within the control arm (TAU alone); this will allow us to explore people’s experiences of receiving ATT and also people’s experiences of being involved in the trial’s control condition.

The trialists will also recruit 15-20 staff members to understand more about their experiences to inform the trial outcomes. Additional interviews will be conducted at 6 monthly intervals with the trial care-coordinator(s) to help inform the training and supervision needs required.

Interviews will be audio-recorded and transcribed verbatim and data will be analysed using Thematic Analysis, resulting in a rich and accessible account of qualitative data. The researcher makes sense of the data and reports themes that emerge The participant interviews will be designed and administered by experienced service-user qualitative researchers (Byrne and Jones) alongside a service user reference group; transcripts will be reviewed and coded by co-applicants (Byrne and Parker) with input from our service user reference group to enable member checking thereby increasing the trustworthiness of the final analysis. Staff interviews will be designed amongst co-applicants (Parker, Wells, Shiers & Haddad) and delivered by the research assistant.

Management of data and analysis will be supported by NVivo. Analysis will occur in parallel with data generation and will continue until thematic saturation is achieved (the point at which no new categories emerge). Based on our previous work it is expected that this will be achieved within 15-20 participant interviews. We will aim to recruit a smaller number of participants from the TAU group (n=10) purposively sampling those who have engaged less well with the trial to

prioritise learning most from those who have had less positive experiences from the trial. Interviews will be supplemented with a survey designed by the service user reference group and sent to all participants.

STATISTICS AND ANALYSIS

The main aims of the feasibility study will be delivered via the continued monitoring of descriptive data and the analysis of data at the end of the last follow-up assessment. This will include reporting data in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement (extension to randomised pilot and feasibility trials) showing attrition rates and loss to follow-up. Analyses of outcomes will not focus on statistical significance, but will concentrate on descriptive statistics and confidence intervals for treatment effects. The proposed primary outcome (PANSS) will be examined using a discrete-time survival model. A detailed statistical analysis plan will be produced by the trial statistician (GD) prior to the examination of outcome data.

An exploratory cost effectiveness acceptability analysis will be used to inform the data required for the economic component of the definitive trial in terms of: the range of costs to be collected; the ability of the QALY to discriminate between groups based on changes in clinical outcomes; factors likely to moderate or influence the incremental cost per QALY ratio to be collected in the definitive trial. At the end of this phase we will be in a position to design a definitive trial with which to evaluate our intervention rigorously against the control condition.

Intervention Type
Other

Primary outcome(s)
1. Recruitment as measured by number of referrals and number consenting and randomised; Timepoint: Baseline
2. Retention as measured by percentage follow-up and questionnaire response rates; Timepoint (s):; 6 weeks, 12 weeks, 6 and 12 months assessment points

Key secondary outcome(s))
1. Attendance at intervention sessions, adherence to between session work as measured by number attended and between session tasks completed; Timepoint(s): 12 weeks
2. Qualitative interview exploring the personal experiences of involvement in the trial (including both arms) using the topic guide; Timepoint(s): 12 weeks +
3. Mental health symptoms – psychosis as measured by Positive and Negative Syndrome Scale (PANSS); anxiety & depression as measured by the Hospital Anxiety and Depression Scale (HADS); drug and alcohol use as measured by the Alcohol Use Disorders Identifical Tool (AUDIT) and Drug Use Disorders Identification Tool (DUDIT); Timepoint(s): 6 weeks, 12 weeks, 6 and 12 months assessment points
4. Metacognitive beliefs and processes as measured by Metacognitions Questionnaire (MCQ-30), Cognitive Attentional Syndrome Scale (CAS) Attentional Control Scale (ACS); Timepoint(s): 6 weeks, 12 weeks, 6 and 12 months assessment points
5. Recovery as measured by the Questionnaire about Process of Recovery (QPR), functioning as measured by the Global Assessment of Functioning (GAF) and quality of life as measured by the World Health Organisation Quality of Life measure (WHOQOL); Timepoint(s): 6 weeks, 12 weeks, 6 and 12 months assessment points

Completion date

30/06/2021

Eligibility

Key inclusion criteria
1. In contact with community mental health services
2. Meets ICD-10 criteria for Schizophrenia, Schizoaffective Disorder, Delusional Disorder or other psychotic disorder not due to a substance or other or known physiological condition.
3. Score four+ on PANSS delusions/hallucinations items 5+ on suspiciousness/grandiosity
4. Help seeking
5. Willing and able to provide written informed consent
6. Aged 16 or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Moderate to severe learning disability (defined by care team e.g. Consultant Psychiatrist or Care-coordinator)
2. Organic impairment (defined by care team e.g. Consultant Psychiatrist or Care-coordinator)
3. Non-English speaking (this would prevent the use of standardised assessments)
4. Inpatient/acute psychiatric care needed
5. No care-coordinator or responsible clinician
6. Primary diagnosis of alcohol/substance dependence
7. Deaf or severely hard of hearing (preventing use of the audio task as part of ATT)

Date of first enrolment
10/09/2018

Date of final enrolment
10/04/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Community Mental Health Teams within Greater Manchester Mental Health NHS Foundation Trust
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20024

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes