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Investigating Attention Control Training in psychosis

Submission date	Recruitment status	[X] Prospectively registered
30/01/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/03/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Attention Training is part of a wider method called Metacognitive Therapy. Metacognitive Therapy (MCT) assumes emotional distress is related to activation of unhelpful forms of perseverative processing such as worry, rumination, self-focused attention, focusing on threat and thought control. These processes are thought to play a central role in the onset and maintenance of many different emotional disorders and problems, including generalised anxiety disorder (GAD), post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD) and depression. Metacognition has also been linked to the development of psychotic symptoms, specifically hallucinations and delusions. Attention training (ATT) is a specific technique aimed at increasing awareness of the flexible control individuals have over thinking. Preliminary studies suggest that ATT is promising in the treatment of auditory and visual hallucinations in psychosis, and a recent study has shown that reduction of worry in people with persecutory ideation also led to reductions in paranoia. ATT has been applied to various other disorders as a brief intervention (4-11 sessions) as well as in psychosis (7-9 sessions) with promising effects. A brief treatment has advantages in relation to resource allocation, costs of delivery within the NHS, minimising waiting lists and could enable patients to achieve social recovery sooner. The present research is an initial study that aims to investigate whether ATT is a feasible and acceptable brief intervention for individuals experiencing difficulties with psychosis.

Who can participate?
The IACT study aims to recruit 40 participants (20 per group) allowing for a drop-out rate of 25%. Individuals within the Greater Manchester West NHS Foundation Trust aged above 16 years that meet the eligibility criteria can take part.

What does the study involve?
Following referral, individuals will be assessed by a member of the research team to ensure that they are suitable. If they are eligible, participants will be randomly allocated to ATT plus Treatment As Usual (TAU) or TAU alone. All participants will have a monitoring appointment at eight weeks and twelve weeks, at which they can discuss their experiences. Those who are allocated to ATT plus TAU will be offered eight sessions of Attention Training.

What are the possible benefits and risks of participating?
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. We have a standardised protocol for managing distress that has been developed with the Psychosis Research Unit Service User Reference Group. 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. In order to reduce any inconvenience caused to the participant, all of the assessments will be completed in a non-stigmatising and convenient location of the participants choice (e.g. their home, their GP surgery or a community venue). Participants that are randomly allocated to ATT plus TAU will have the benefit of receiving a brief and non-invasive intervention that has been found to have enduring effects, without a lengthy waiting list. For participants that are not receiving ATT, having regular assessments is considered a potential benefit given that it presents an enhancement from routine care as psychotic symptoms will be monitored more regularly and in a more comprehensive manner. Involvement in this study has the potential to provide commissioners with valuable data for improving choices for consumers in the future. As the intervention is brief and non-invasive, it could be potentially beneficial for IAPT services and mental health nurses. Therefore, this would benefit future service users and carers by proving more options for reducing distress and improving quality of life.

Where is the study run from?
Greater Manchester West NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2014 to November 2015

Who is funding the study?
Greater Manchester West NHS Foundation Trust (UK).

Who is the main contact?
Dr Sophie Parker
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A study to investigate the role of attention in psychotic symptoms and the feasibility and acceptability of using attention training as a strategy for individuals with psychosis

Acronym
IACT

Study objectives
The primary hypothesis of the proposed study is that Attention Training (ATT) plus Treatment as usual (TAU) will improve psychotic symptoms compared to TAU alone, measured using a psychiatric interview (PANSS). In addition, secondary hypotheses include:
1. ATT plus TAU will lead to improved quality of life compared to TAU alone
2. ATT plus TAU will lead to a reduction in affective symptoms and negative symptoms compared to TAU alone
3. ATT plus TAU will be cost effective compared to TAU alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Greater Manchester West, 25/02/2014, ref: 14/NW/0043

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
http://www.psychosisresearch.com/wp-content/uploads/2014/02/Participant-Information-Sheet-V2doc.pdf

Health condition(s) or problem(s) studied
Schizophrenia, schizoaffective disorder or delusional disorder

Interventions
Patients are randomised to two groups:
1. Intervention: The intervention group will receive Attention Training (n=20). ATT will be delivered over eight sessions. During these sessions, participants will be assisted in developing their skills in selective attention, rapid attention, switching and divided attention, in a process lasting approximately 12 minutes. This is done using an auditory modality, research has shown this to have greater success than using visual tasks. Participants will also 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 health care professional trained to deliver ATT and working under supervision from a Clinical Psychologist. Each session will last approximately 30 minutes and will consist of an overview of how things have been in the last week including any practice issues, administration of assessments due, followed by the 12 minute auditory attention training task.
2. Control: The control group will receive treatment as usual plus follow-up (n=20). This will include comprehensive monitoring at eight weeks and twelve weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility will be measured using referral rates, recruitment, attendance at sessions, adherence to between-session work, and follow-up and questionnaire response rates.

Secondary outcome measures
1. The PANSS (Positive and Negative Syndrome Scale): a structured clinical interview assessing positive and negative symptoms of psychosis occurring within the last seven days
2. The HADS (Hospital Anxiety and Depression Scale): a self-report measure of anxiety and depression
3. The MCQ-30 (Meta-cognitions Questionnaire): a 30-item self-report measure of meta-cognitive beliefs
4. The CAS (Cogntive Attentional Syndrome Scale): a short self-report measure of cognitive attentional syndrome activation in the last seven days
5. The ACS (Attention Control Scale): a 20 item measure designed to assess general capacity to control attention
6. The WHOQOL: a questionnaire assessing quality of life of the participant
7. The QPR (Process of Recovery Questionnaire): a service user designed measure of recovery
8. Finally, a self-attention rating scale will be administered after the first and second ATT session for those randomly allocated the ATT plus TAU arm. The scale will utilise a likert rating to

measure current intensity of self-focus on a scale ranging from -3 (entirely externally focussed) to +3 (entirely self-focussed).

Overall study start date
01/03/2014

Completion date
01/11/2015

Eligibility

Key inclusion criteria
1. In contact with mental health services
2. Either meets ICD-10 criteria for schizophrenia, schizoaffective disorder or delusional disorder, or meet entry criteria for early intervention In psychosis services (operationally defined using the PANSS)
3. Score at least four on PANSS delusions or hallucinations items
4. Help seeking
5. Competent and willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Moderate to severe learning disability
2. Organic impairment
3. Non-English speaking (this would prevent the use of standardised assessment instruments)
4. Inpatient/acute psychiatric care needed
5. Does not have a care coordinator or responsible clinician
6. Substance dependency
7. Deaf or hard of hearing (this would prevent use of the audio task as part of the intervention)

Date of first enrolment
16/05/2014

Date of final enrolment
01/11/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Prestwich Hospital
Manchester
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Sponsor information

Organisation
Greater Manchester West NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Greater Manchester West Mental Health NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No