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Manualised anger management intervention for people with mild to moderate learning disabilities

Submission date
07/07/2009

Recruitment status
No longer recruiting

Registration date
14/07/2009

Overall study status
Completed

Last Edited
03/06/2016

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many people with learning disabilities find it hard to control their anger. This often leads to aggression, which can have serious consequences, such as exclusion from mainstream services and the need for potentially more expensive emergency placements. Anger management teaches people to recognize what makes them angry and learn skills that they can use to cope better with those situations. Several small studies of anger management groups for people with learning disabilities have shown promising results. All of the published studies have reported that people who take part in an anger management group show less anger at the end than people who are waiting for treatment, and they stay less angry for several months afterwards. The aim of this study is to evaluate the effectiveness of an anger management intervention for people with mild to moderate learning disabilities.

Who can participate?
Adults aged 18 to 65 attending a service for people with mild to moderate learning disabilities, and identified by service staff as having problems in managing their anger.

What does the study involve?
Participants are randomly put into one of two conditions, according to which day service they attend. Half of them take part in staff-led anger management groups. The other half are supported as usual by staff while they wait for treatment (waiting-list group). Anger management is usually taught by Clinical Psychologists. In this study, the group therapy takes place in the services that the service users attend during the day, and the therapists are staff in those services. A Clinical Psychologist teaches the staff how to work with a treatment manual. The manual was written for use by therapists who have never done this before. It gives full details of how to run each session of a 12-week anger-management course. At the end of the 12 weeks, there is a six-month follow-up period. Then the staff who work with the waiting-list groups are taught how to use the manual, so that the waiting-list groups can also be offered anger management. We train the staff how to use the manual; then, when the groups are running, we check that the staff are running them properly and if they are running well; and at the end, we talk to staff about how they found it to run a group and if there has been any effect

on the rest of their service. The main point of the study is that we assess how well people are doing before and after they take part in an anger management group, and six months later. We measure how angry and aggressive people get and how well they cope with difficult situations, both in the service and at home, how they feel about themselves, and what they thought of the group. We also find out if it costs less to support people after they have been part of an anger management group. We do all this by talking to the service users themselves, their key-workers in the service, and their home carers.

What are the possible benefits and risks of participating?
The potential benefit to participants is that participants will learn to express their anger more appropriately, with a decrease in aggression, so increasing their opportunities for social inclusion, and decreasing the risk of placement breakdown, exclusion from services, and involvement with the criminal justice system. We believe there to be no significant risks to participants or society. There is a hypothetical risk that a client's condition could be worsened by participation in the group, but the likelihood of this happening is extremely small.

Where is the study run from?
Abertawe Bro Morgannwg University NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2009 to December 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Paul Willner

Contact information

Type(s)
Scientific

Contact name
Prof Paul Willner

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/53/34

Study information

Scientific Title
A multi-centre phase III cluster randomised controlled trial of a manualised anger management intervention for people with mild to moderate learning disabilities

Study objectives
To evaluate the effectiveness, compared to normal care, of a manualised anger management intervention, delivered to people with mild to moderate learning disabilities in a service setting, in reducing levels of reported anger.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/085334
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/52962/PRO-08-53-34.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales REC - Panel C, 19/06/2009, ref: 09/SWE03/41

Study design
Multicentre phase III cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mild to moderate learning disabilities, anger management

Interventions

Day care centres will be randomised to receive either a manualised cognitive behaviour therapy (CBT) intervention consisting of 12 weekly psycho-educational group sessions supplemented by 'homework' or usual care. Participants in both groups will be followed up for 6 months post-intervention.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Provocation Index (PI) as completed by the service-user, at follow-up. The PI is a direct measure of felt response to defined situations that may provoke anger and has frequently been used with this service-user group for the current purpose.

Outcome measures will be taken at baseline, immediately after the support as usual (SAU) or intervention in both groups in parallel and 6 months after the completion of the intervention or SAU.

Secondary outcome measures
Validated questionnaires will be completed to assess the following domians:
1. Anger (assessed by the PI) as completed by a key-worker and a home carer
2. Aggression will be assessed by key-worker report using the Irritability domain items of the Aberrant Behaviour Checklist (ABC) and the Modified Overt Aggression Scale (MOAS)
3. The Profile of Anger Coping Skills (PACS) will be completed by both service-user, home carer and key-worker to assess the development of alternative, more functional coping skills
4. Mental health will be assessed by using the Glasgow Depression and Anxiety Scales and an adaptation of the Rosenberg Self-Esteem Scale for people with a learning disability
5. Self-reported quality of life will be assessed by using the Comprehensive Quality of Life Scale - Intellectual Disability (ComQoL-ID)
6. Key-workers' attributions in respect of challenging behaviour will be measured by the Controllability Beliefs Scale (CBS)

Additionally, interview data for qualitative analysis will be collected from participants, therapists and service managers, and a health economic evaluation will be undertaken of the costs and consequences of the invervention.

Outcome measures will be taken at baseline, immediately after the support as usual (SAU) or intervention in both groups in parallel and 6 months after the completion of the intervention or SAU.

Overall study start date
01/07/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria

Services:
1. Reported anger control problems among at least four service users who meet individual inclusion criteria and want to participate
2. Availability of at least two staff members willing to be trained as group leaders
3. Service manager provides written agreement to participate

Service Users:
1. An adult attending a service for people with mild to moderate learning disabilities
2. Identified by service staff as having problems in managing their anger
3. Wishing to learn to improve their anger management
4. Able to provide informed consent
5. Able to complete the assessments
6. Aged 18 to 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
Services:
1. The service is already running an anger management programme similar to this one
2. There are no suitable facilities for group work

Service Users:
1. Attending the service for a reason other than a diagnosed learning disability
2. Currently receiving psychological treatment for anger or aggression
3. Urgently requiring referral to a Clinical Psychologist for individual treatment of anger or aggression
4. Experiencing circumstances which indicate that a Protection of Vulnerable Adults (POVA) procedure should be initiated
5. If for any other reason the supervising Clinical Psychologist makes a clinical judgement that participation in the group would be counter-indicated

Date of first enrolment
01/07/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Abertawe Bro Morgannwg University NHS Trust
Neath
United Kingdom
SA11 1DJ

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
30 - 36 Newport Road
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CF24 0DE

Sponsor type
University/education

Website
http://www.cf.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	09/02/2011		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	01/09/2013		Yes	No