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Guided self-help for depression in adults with autism: a feasibility study

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
28/09/2016

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a common disorder that affects the way that a person communicates and relates to others. It is a spectrum condition the level of disability is spread across a wide range, from almost unnoticeable to completely debilitating. In general however, the difficulties sufferers experience tend to fall into social communication (speech and body language), social interaction (recognising and expressing emotions) and social imagination (being able to understand and predict other people's behaviour). It has been found that at least 30% of adults with ASD experience depression (low mood). Cognitive Behaviour Therapy (CBT) is a type of talking therapy which works by changing the way a person thinks and behaves. It is the recommended treatment for mild-moderate anxiety and depression in the NHS and is usually 'low intensity' CBT. This means that it involves guided self-help with individual support from a Psychological Wellbeing Practitioner (PWP) or psycho-education (education offered to people to help empower them and deal with their condition) as part of a group. There is some evidence that CBT can be helpful for people with ASD and anxiety if adapted for their needs. However it is not known if CBT can also be adapted and be helpful for depression in this group. The NHS guided self-help materials for depression have not been developed for people with ASD who can have a different style of processing information. Furthermore, some NHS therapists know about the needs of people with ASD but some do not. Receiving information as part of a group may be difficult for people with a diagnosis of ASD and they may find the social aspect of the group stressful. In this study, the researchers are working to develop self-help materials for depression specifically for adults with ASD and to produce an accompanying therapist guide. The aim of this study is to find out if these materials are acceptable to patients and to find out whether a larger study looking at their effectiveness is feasible.

Who can participate?
Depressed adults who have been diagnosed with ASD.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive treatment as usual. This may involve no treatment, anti-depressant medical, referral to a specialist or therapy. Those in the second group take part in a guided programme of self-help CBT for depression. This involves nine individual sessions of adapted guided self-help with the

support of a psychological therapist/coach who will receive training and supervision in working with people with ASD. At the start of the study and then again after 10, 16 and 24 weeks, participants in both groups have their depression levels measured. In addition, the number of participants who took part is recorded in order to see if a larger study would be feasible.

What are the possible benefits and risks of participating?
It is not known whether participants will benefit from taking part in this study. There is a risk that people with depression will not be receiving an effective treatment. Participants receiving Guided Self-Help will be monitored and if their depression is getting significantly worse and it seems they need more intensive help with their depression, then they will stop the Guided Self-Help and will be referred for a higher level of support.

Where is the study run from?
Autism services in Avon & Wiltshire Mental Health Partnership NHS Trust and Northumberland, Tyne and Wear NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2015 to May 2018

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Ailsa Russell (public)
2. Dr Kate Cooper (public)
3. Dr Stephen Barton (public)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Funder reference number 14/43/02

Study information

Scientific Title
Adults with Autism and Depression, low intensity cognitive behavioural treatment compared to treatment as usual – a feasibility study

Acronym
ADEPT

Study objectives
The aim of the study is to develop guided self-help materials for depression for adults with autism and to consider the feasibility of a randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, 15/04/2016, ref: 16/ WA/0077

Study design
Feasibility randomised controlled trial with nested qualitative evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Depression in Adults with Autism

Interventions
Participants will be randomly allocated to Guided Self-Help or Treatment as Usual. Randomisation will be by means of an automated telephone service and will be stratified by study centre and minimised by depression severity and anti-depressant medication.

Guided Self-Help group: Participants will attend a 1 hour introductory session and then 8 individual sessions with a therapist coach lasting up to 45 minutes. They will be provided with session materials based on the principles of Behavioural Activation. The therapist coach will serve as a guide to work through the materials during the session and encourage between-session planned activities. There will be an accompanying therapist manual. The session materials will be adapted for adults with Autism. The intervention will be delivered over a maximum of 10 weeks. The therapist will be a 'low intensity' cognitive behaviour therapist or Psychological Wellbeing Practitioner (PWP) i.e. a therapist working at the low intensity step of the care pathway for depression who has knowledge of cognitive behavioural theory of psychological problems and training/experience in delivering manualised interventions. They will not ordinarily have the knowledge and training to develop individualised, formulation driven interventions for psychological problems.

Treatment as Usual group: Participants will be recommended referral to local psychological treatment services for depression via their General Practitioner. This may include:
1. No treatment
2. Signposting for self-referral to IAPT services
3. Autism clinician recommendation to the GP to make a referral to IAPT services
4. Clinic or GP referral to secondary care mental health services
5. Anti-depressant medication

Participants in both groups will attend follow-up at 10, 16 and 24 weeks post-randomisation.

Intervention Type

Behavioural

Primary outcome measure
Feasibility outcomes:
1. Proportion of adults with Autism consenting to the study is determined through recording the number of eligible participants who consent to participate
2. Proportion completing the baseline assessment and entering the randomised phase is determined through recording the number of consenting participants who complete the outcome measures at baseline
3. For those in the intervention group, the number of guided self-help sessions attended and the proportion completing 5 or more sessions is assessed through ongoing participant data collection
4. Proportion completing follow-up assessments is determined through recording the proportion of consenting participants who complete the outcome measures at 10 and 16 weeks post-randomisation

Primary clinical outcome:
Depression is measured using the Patient Health Questionnaire (PHQ-9), Beck Depression Inventory-II (BDI-II) and the Hamilton Rating Scale for Depression at baseline, 10, 16 and 24 weeks

Secondary outcome measures
1. Obsessive Compulsive symptoms are measured using the Obsessive Compulsive Inventory (OCI-R) at baseline, 10, 16 and 24 weeks
2. Levels of anxiety are measured using the General Anxiety Disorder Questionnaire (GAD-7) at baseline, 10, 16 and 24 weeks
3. Emotional experience will be measured using the Positive and Negative Affect Schedule (PANAS) at baseline, 10, 16 and 24 weeks
4. The impact of problems on everyday life will be measured using the Work and Social Adjustment Scale (WSAS) at baseline, 10, 16 and 24 weeks
5. Quality of Life is measured using the EQ-5D-L at baseline, 10, 16 and 24 weeks
6. Social function is measured using the SF-12 at baseline, 10, 16 and 24 weeks
7. Repetitive behaviours are measured using the Repetitive Behaviours Questionnaire (RBQ-2) at baseline, 10, 16 and 24 weeks
8. Rumination is measured using the Rumination Refection Questionnaire (RRQ) at baseline, 10, 16 and 24 weeks
9. Resource and Service Use is measured using a pilot Resource and Service Use questionnaire at baseline, 10, 16 and 24 weeks

Overall study start date
01/12/2015

Completion date
30/05/2018

Eligibility

Key inclusion criteria
1. Adults (aged 18 years and over)
2. Clinical diagnosis of an Autism Spectrum Disorder (ASD)
3. Current depressed mood

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Where Intellectual disability is known or suspected as the materials have not been developed for this group
2. Current risk of suicide such that a low intensity intervention would not be clinically appropriate
3. Psychosis
4. Current alcohol/substance dependence
5. Untreated epilepsy
6. Attendance at >6 sessions of a cognitive behavioural intervention (CBT) during the past 6 months
7. Non-English speaking

Date of first enrolment
01/10/2016

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Adult Autism Service (BASS)
Avon & Wiltshire Mental Health Partnership NHS Trust
Petherton Resource Centre

Bristol
United Kingdom
BS14 9BP

Study participating centre
Adult Autism Diagnostic Service
Northumberland, Tyne and Wear NHS Trust
Keegan Court
Grassbanks
Gateshead
United Kingdom
NE10 8DX

Sponsor information

Organisation
Avon & Wiltshire Mental Health Partnership NHS Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0379k6g72

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
Publication in a high impact, peer-reviewed journal.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to not gaining ethical approval or consent from participants to share such data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	23/12/2019	Yes	No
Protocol article	protocol	03/12/2017	27/11/2020	Yes	No
Results article		29/11/2019	11/10/2023	Yes	No